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**BALA BUDGET ACT OF 1997: IMPACT ON
C T SAVINGS AND PATIENT CARE**

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HEARING
BEFORE THE
SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT
OF THE
COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS
FIRST SESSION

SEPTEMBER 15, 1999

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BALANCED BUDGET ACT OF 1997: IMPACT ON COST SAVINGS AND PATIENT CARE

WEDNESDAY, SEPTEMBER 15, 1999

**HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
*Washington, DC.***

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Stearns, Greenwood, Deal, Burr, Bilbray, Whitfield, Ganske, Norwood, Cubin, Shadegg, Pickering, Bryant, Bliley (ex officio), Brown, Pallone, Deutsch, Stupak, Green, Strickland, DeGette, Barrett, Capps, Hall, Towns, Eshoo, and Dingell (ex officio).

Staff present: Tom Giles, majority counsel; Pat Morrissey, majority counsel; Robert Simison, legislative clerk; Bridgett Taylor, professional staff member; and Amy Droskowski, professional staff member.

Mr. BILIRAKIS. Good morning. I am being accused of diverting the hurricane from Florida and sending it to Virginia and messing up Mr. Bliley's boat, the chairman's boat. So I had better get this hearing started.

Well, I am pleased to convene this hearing on BBA 1997. It is time certainly for us to step back and review the impact of the BBA on providers and beneficiaries, and certainly we have been doing that for some time.

Just over 2 years ago we enacted landmark changes to the Medicare program. Many of these changes were designed to provide for more beneficiary choice and to help guarantee the solvency of the Medicare program well into the next century.

I am proud of that legislation and this committee's vital role in its creation. The BBA was enacted with bipartisan support and I believe it is critical that we work together in considering any changes to the law.

I am pleased to report that we are achieving many of the objectives of the BBA. Wasteful spending is down; medical solvency has been extended and many seniors have increased access to health care services and providers. Also, the amount of money lost to the Medicare program through fraud and abuse has dropped considerably due to the new abilities of the Department of Health and Human Services' Inspector General and the Justice Department.

However, as we all know, and the room is full, the BBA has also had some unfortunate unintended consequences. In some cases

more savings were realized from providers than originally anticipated. In other cases, HCFA has failed to act in a manner consistent with beneficiaries' interests and congressional intent. We hope to address these problems through legislative action this year.

Today we will hear from both providers and HCFA about the most recent problems facing the Medicare program. This subcommittee has already held two hearings on issues related to Medicare Plus Choice and I am committed to protecting seniors' health care options under that program.

This hearing will focus on a multitude of other areas affected by the BBA. As we begin crafting legislation to correct some of these unintended consequences, the testimony from this hearing will help us make informed decisions about the scope of any legislation.

I am very interested in hearing from our distinguished panels today and obviously am grateful to them for taking time away from their schedules to be here. Each witness can provide valuable insight into the effects of the BBA on providers and on beneficiaries' access to health care services. With the imminent implementation of a prospective payment system for hospital out-patient departments and home health agencies, we hope to hear some constructive suggestions about how these regulations can best be refined.

However, I would caution that the days of runaway Medicare spending are over. While we work to ensure patients' access to necessary services we must remain vigilant guardians of public funds. As we draft legislation to amend BBA, we certainly will not be re-opening every provision.

Funds must go to those areas of demonstrated and compelling need. HCFA, however, must also be sensitive to the legitimate issues raised by many of the provider groups here today. Many of these concerns can, and should, be resolved administratively, and I would like to emphasize that. Many can and should be resolved administratively, and we will get into that later with our witnesses.

One particular area is the plight of the cancer hospitals. I ask HCFA to work with this committee to revise the ambulatory patient classification, APC system, in a manner consistent with statutory intent. The proposed APC system will erode patient quality and access to needed services. If the current proposal becomes effective, many procedures will simply migrate to the more expensive in-patient settings, thus ultimately increasing costs to the Medicare program. Site of service recommendations by providers will be made with an eye toward reimbursement levels rather than focusing on patient access and convenience.

This is just one issue that I hope we can address today. Obviously there are many.

Again I would like to thank our witnesses who will testify and I particularly appreciate, and I want to accent this, appreciate HCFA's agreement to have a high-level official present for the duration of the hearing to better understand and take notes and share back with his or her HCFA personnel the stakeholder issues. I look forward to productive dialog and I recognize Mr. Brown for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman.

I am glad, Mike, you could join us today and I would like to welcome other distinguished witnesses to the three panels.

Mr. Chairman, I want to commend you for arranging this hearing. Our subcommittee surely has a lead role in addressing concerns related to the Medicare provisions of BBA, and this hearing is timely and appropriate.

Our focus today reflects the subcommittee's jurisdiction over Medicare Part B. We cannot appreciate the impact of the Part B changes unless they are viewed in the context of the entire package of cuts. Providers have surely been hit from all sides.

I am sure all of my colleagues, like me, have received hundreds of letters and postcards, faxes and phone calls in the aftermath of BBA. Health care administrators and providers whom I have known for years and whose counsel I value very highly say the BBA cuts are jeopardizing their financial viability and compromising access to care.

These are serious issues. Congress must address them. Access, quality and universality are the foundations of Medicare and BBA cuts have potentially placed two of those three at risk. I cannot emphasize strongly enough that we need to assess the BBA concerns now because what providers are telling us is that if the damage is being done now, much of it will be irreversible.

I also cannot emphasize strongly enough to those of you who are living with the BBA changes the importance of providing Congress with information that can help us determine what the next steps actually are. We need to know specifics. We need to get a sense of how BBA is affecting health care on a day to day basis, to the greatest extent possible see analysis and data that target the worst trouble spots.

This information is critically important because we cannot turn back the clock. One of the reasons we cannot turn back the clock relates to the three foundations of Medicare that I mentioned a moment ago: quality, access and universality. As the premium support campaign clearly illustrates, any changes we make in Medicare can be coopted for purposes that could ultimately undermine all three objectives.

When we lose BBA savings we are not only accelerating Medicare insolvency; we're risking the consequences of making Medicare a more expensive program to run. What I mean by this is every step we take that weighs Medicare down provides fodder for privatization—the "Medicare is too expensive, managed care plans can do it better" rhetoric. And that is a big price to pay. If providers think it is an uphill battle with Medicare, just wait until managed care gets hold of it. If we are worried about access and quality now, wait until Medicare beneficiaries' only choice is a managed care plan.

Mr. Chairman, I want to raise one more issue that I believe is inextricably linked and tied to any discussion of BBA fixes—tax cuts. If your representative tells you that he favors or she favors BBA fixes and also says that she favors or he favors a tax cut, let's say in the \$600 billion, \$700 billion, \$800 billion range, they are either being disingenuous or they are looking at a very, very different Federal budget.

Tax cuts anywhere near that size would not only obliterate any flexibility to restore BBA funding; the BBA cuts would pale, the

BBA cuts that many providers have received, have been hit by, would pale in comparison to what providers would face in the years ahead if a large tax cut goes forward.

This is not a threat; it is a fact. The \$792 billion majority tax cut proposal assumes one, favorable economic conditions will be locked into place for a decade. Two, it assumes no emergency spending during those 10 years. Three, it would require a 10 to 12 percent reduction in every Federal program. Think about that. Medicare Part B comes out of general revenues. If there is a \$790 billion tax cut, austerity, severe cuts would be our only option.

We have been through this before. I think many of us in this room recall the original BBA envisioned cutting Medicare and Medicaid by \$270 billion. Against the odds, we defeated that. But as we look at the pain caused by BBA savings so far, I urge you to keep in mind what we could be facing if our resources now and in the future, even the resources we need to support current Medicare spending, if our resources now and in the future are instead channeled into tax cuts. Beware. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bliley, chairman of the full committee, for an opening statement.

Chairman BLILEY. Thank you, Mr. Chairman. I would ask unanimous consent to put my full statement in the record.

Mr. BILIRAKIS. Without objection, the statement of all members of the panel will be made a part of the record.

Chairman BLILEY. Mr. Chairman, I thank you for having this hearing. I did not know that there were so many providers of health care in Virginia until we did the BBA but I think I have seen them all and the story is pretty much the same, that we have gone too far with these cuts, that hospitals are hemorrhaging, that HCFA promised that if the hospitals did due diligence on trying to collect bills, that they would reimburse them 100 percent for their losses. Now they have cut it to 50 percent.

The DRG, which says that if a procedure calls for a 3-day stay in a hospital and if the hospital is efficient and gets the patient out in 2 days and they go to a skilled nursing home, HCFA cuts back on the reimbursement. However, if the patient has to stay longer, they do not get any extra for that. The same is true for home health. The same is true for out-patient.

I want to thank the administration for having your staff here to hear all the witnesses and I would like for the administration to submit in writing for the record a list of all the concerns you hear today that seek a change in policy. Please let us know what you feel you have the authority to fix and what you feel needs congressional action. To the extent you can provide as extensive a rationale for your decision would be helpful. I look forward to reviewing your responses.

I thank you, Mr. Chairman, and I am going to be in and out because there is another hearing downstairs in the Telecommunications Subcommittee that I need to make an appearance at.

[The prepared statement of Hon. Tom Bliley follows:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Thank you, Mr. Chairman.

I am pleased that the Health and Environment Subcommittee is holding this hearing today. This Committee made some very important changes to the Medicare program two years ago, and it is important to monitor the impact those decisions have on our health care delivery system. In particular, I am most interested in knowing of any unintended consequences that may have an adverse affect on access to care.

In the Balanced Budget Act of 1997, this Committee made some difficult decisions in how best to address the concern of the Nation that the Medicare program was facing financial ruin, and changes needed to be made. Some significant changes were enacted. Moving to a prospective payment system for hospital outpatient department services, skilled nursing facility services and home health services helped reduce federal spending by \$115 billion over 5 years, and created new efficiencies within the Medicare program. I am proud of the BBA 97 for that reason.

Now there has been much discussion about revisiting some of those tough policy decisions we made two years ago. As this Committee considers BBA 97 refinements, I hope we learn today from our witnesses that the Administration has done all it can within the law to foster the best, most efficient patient care.

This Committee takes a dim view of regulations that exceed their statutory basis, or when the Administration doesn't do enough within its administrative authority to meet the legitimate concerns of the American people. That is why I hope we will continue this series of formal inquiries by this Committee into this important program and its implementation.

I look forward to hearing from our witnesses today. In addition, I am hopeful that representatives from the Health Care Financing Administration are able to comply with the request Mr. Bilirakis made when he invited you to this hearing, that you will be able to stay to listen to all of the witnesses before us today. At previous hearings, we have heard concerns some witnesses have raised regarding HCFA's implementation of laws affecting the health care industry. I think it would be valuable for HCFA to stay to hear those concerns first hand.

Again, Mr. Chairman, thank you for convening this hearing today.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Thanks for being here. Mr. Pallone for an opening statement.

Mr. PALLONE. I want to thank the chairman for holding this hearing. The Balanced Budget Act's impact on the hospitals in my home State of New Jersey has been severe and unfortunately is getting worse.

The situation is so bad in New Jersey that hospitals are starting to close. Memorial Medical Center at South Amboy in my district recently closed its doors to new patients during the break. And just last Friday, St. Clair's Hospital in Dover, New Jersey announced its closure as an acute care facility.

I have been working, Mr. Chairman, with the New Jersey Hospital Association to identify the worst of the problems affecting New Jersey's hospitals and I would just like to briefly run through them.

The first I want to mention is the out-patient prospective payment system, PPS. HCFA's interpretation, which exceeds congressional intent, would reduce hospital out-patient payments by 5.7 percent nationwide. In New Jersey, however, this view of the BBA will cost hospitals 16.6 percent on average and 40 percent of New Jersey's 85 acute care hospitals have a negative Medicare operating margin. This is unacceptably low and unfair, in my opinion.

Accordingly, while I am not opposed to an equitable PPS system, I am opposed to the one HCFA has proposed. An appropriate remedy to this problem would be either to try a demonstration project first or to postpone the implementation of the PPS system altogether until a better one can be developed.

Second, Mr. Chairman, graduate medical education payments needs to be rebased on data more current than 1984. New Jersey was under a Federal waiver from 1983 to 1989 and was not re-

quired to file Federal Medicare cost reports. Consequently, the data from which the New Jersey teaching hospitals are paid does not adequately reflect New Jersey's teaching costs. A targeted rebasing plan for those States that are reimbursed less than 70 percent of their costs based on 1996 data would benefit hard-hitting teaching hospitals.

Third, Mr. Chairman, the Medicare transfer policy is flawed. The expansion of the definition to include Medicare patients who are sent from an acute care hospital to any postacute setting inhibits a hospital's ability to seek patient treatment in an appropriate setting. The BBA moreover, allowed for this expanded definition to be applied to further patient treatments, and this is having or will have a devastating effect on New Jersey's hospitals.

More than 24 percent of New Jersey's seniors seek additional care after a hospital stay and the cost to New Jersey's hospitals will be \$18 million a year. The transfer provision penalizes efficient hospitals. The expansion of the transfer provision to other patients is also a problem.

Fourth, the skilled nursing facilities, PPS, is also flawed. It is inadequate for individuals with complex medical needs. Because of the poor reimbursement rates for patients in skilled nursing facilities, patients are increasingly seeking placement in hospitals instead of in the most appropriate settings. This, in turn, increases the length of hospital stays, leaving hospitals susceptible to criticism for not discharging patients fast enough. And this cycle could and should be changed. In my view, HCFA needs to accurately recognize the added costs of nontherapy ancillary services for skilled nursing facility patients.

And fifth and finally with regard to the hospital concerns, while Congress alleviated some of the financial burdens associated with the interim payment system for home health care providers, with regard to home health care now, more needs to be done. The 15 percent across-the-board reduction in payment rates that will take effect on October 1, 2000 if a PPS system is not implemented will crush New Jersey's home health providers who provide the care at rates well below the national average of home care spending per patient and the 15 percent across-the-board reduction obviously is a problem.

Mr. Chairman, I just want to say that because New Jersey's hospitals cannot afford to wait, I am working on legislation that would correct these problems. But before closing, I wanted to mention two more concerns arising from the BBA.

Earlier this year I joined my colleague from North Carolina, Mr. Burr, in introducing the Medicare Rehabilitation Benefit Improvement Act. This bipartisan effort would amend the \$1,500 caps imposed by the BBA on physical and speech therapy and occupational therapy. Specifically it would provide for exceptions, allowing certain Medicare beneficiaries to obtain services beyond the \$1,500 caps. These caps are denying some of the most vulnerable seniors, particularly stroke victims and those with multiple injuries or diseases in a single year, much-needed therapy, and exceptions need to be made.

And last, Mr. Chairman, I wanted to mention the impact on Medicare Plus Choice. I know we had hearings on this and that is

not the topic today but over the August recess I heard from many frightened seniors who were concerned about Medicare Plus Choice providers pulling out of their service areas and I have come to the conclusion that the cuts in payments to Medicare Plus Choice providers are too steep. Providers that are paid well do not leave the program, in my opinion, or scale back benefits. One legislative option I am considering would increase the payment floor for Medicare Plus Choice providers relative to the fee-for-service payments.

I know that my colleagues, and I think rightly so—I listened to what Mr. Brown said in particular—we all realize that we cannot make every change and increase everything with regard to the BBA but I do think that we are starting to see some major problems now, particularly with regard to hospitals. And my response, particularly with regard to New Jersey's hospitals, is based on the concerns that I saw, the actual closings of hospitals that have occurred within the last month or 2.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman and I would suggest to the gentleman that the scope of this hearing is intended to include the impact on cost savings and patient care regarding not only how the Balanced Budget Act was crafted but also how it is being interpreted by HCFA. So the points that you make are clearly intended to be a part of this hearing.

Mr. Greenwood for an opening statement.

Mr. GREENWOOD. Thank you, Mr. Chairman. I will be brief.

This is a very, very important hearing and I thank the chairman for holding it. Whatever metaphors we use to describe the unintended consequences of the Balanced Budget Act of 1997, throwing the wheat out with the chaff or the baby out with the bathwater, cutting bone when we were trying to cut fat, the fact of the matter is that the corrections were too severe.

When you are in this business any amount of time, I think you can judge sincerity and when I meet with my hospital representatives, my home health care agencies, when I meet with my skilled nursing facilities, I can sense the sincerity of their dilemma. It is real.

But it is also important that we correct our course here and that we not back-track. The worst that we could do is be sitting around in 2001 having a hearing about how we overreacted in 1999 to the way that we overreacted in 1997, and keep the yo-yo going up and down. So we need to find the right course here and I am confident that with these hearings we will begin that process.

I yield back, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman, for holding this very important hearing and good morning to you, to all my colleagues and to the distinguished individuals that are here today to offer their testimony for us.

Like so many of my colleagues, I too have heard the complaints—I think that they are legitimate; I think that they are real—from my health care providers in my wonderful congressional district and they are all about what we did in the Balanced Budget Act of 1997.

Hospitals, home health agencies and nursing homes across our country say they cannot live within the budget cuts we enacted just 2 short years ago.

A recent Lewin Group study found that payments to health care providers are already \$40 billion lower than we anticipated when we passed the BBA. The study conducted by the American Hospital Association warns that the BBA cuts could leave seven out of 10 hospitals to operate with negative Medicare margins within 3 years.

Before coming to the House, I served as the chair of a county hospital board of directors for almost 10 years. I was very, very involved in the day-to-day operations, in the overall health care for 650,000 people in San Mateo County, California. So I know that a hospital cannot continue to offer services on a negative margin.

So something obviously has to give. And what I fear is that the thing that is actually giving is patient care. There are the providers but the real face to all of this are the people that receive the care. Without relief, hospitals, home health agencies and nursing homes are faced with two options. They either cut back services or withdraw from the Medicare program altogether.

And it is already happening in many quarters across the country. In the first year following enactment of the BBA, nearly 25 percent of home health agencies in our country closed their doors. The result: over 500,000 fewer seniors received home health services in 1998 than in 1996. I think for a great Nation obviously we can do much better than this.

The \$1,500 annual cap on physical and speech therapy is forcing some beneficiaries recuperating from strokes, suffering from Parkinson's disease and multiple sclerosis to prematurely end needed therapy.

So it is my sincere hope, Mr. Chairman, that this hearing is just the first step in a very real serious examination of not only the issues that each one of us is outlining as we make our opening statement but that out of this will come an insurance policy, so to speak, to those that participate in these programs, that need to participate in these programs, that they will continue to have access to solid, good quality health care in the greatest country on the face of this earth.

I understand that the leadership not only of this committee but of Ways and Means, and I think that you touched on this in your opening statement, Mr. Chairman, are working on a BBA fix bill. I look forward to that. I will roll my sleeves up and work with you.

I just want to add a footnote to this. I know that our ranking member talked about the tax cuts. I think that it is very important for Members of Congress to have credibility obviously with the American people. From the earliest days of this nation, Congress, of course, by poets and writers has always been the brunt end of jokes. But we have an opportunity here. We know what the truth is, what is going on, because we go to our districts every week. The chairman of the Commerce Committee stated that he never realized that there were so many providers in his State and he has met with every single one of them.

So we have our finger on the pulse of what is going on. We know this. We are going to hear it in a much clearer way and hear from professionals today.

It is very important for the Congress and the majority party, who are in charge of governing here, that we tell the truth about the caps. No. 1, caps have worked. That is why we continue to accrue the benefits in terms of our Nation's budget.

But we also have to tell the truth about the caps that were set and maybe were not set right a few years ago. We should have the courage of our convictions to reset those caps, and we can do this. We can still be fiscally responsible and be responsible to the people of our Nation in the area of health care that they need the most.

This is not something that you can say, "Take it or leave it." Ask a Member of Congress if they are willing to take it or leave it in terms of their own health care or our children's or our spouse's or our parents'. We would say no to that. The same thing with the family of the American people.

So thank you for holding this hearing. I look forward to not only the testimony but the outcomes that I am very sure that we can not only grapple with but on a very fair and honest basis, do something about it. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentlelady.

Dr. Ganske for an opening statement.

Mr. GANSKE. Thank you, Mr. Chairman. I appreciate your having the hearing and I am sure that you are concerned about what is going on with Hurricane Floyd and have important things on your mind, but this is important, too.

I have rural hospitals in my district that are on schedule to lose \$1 to \$2 million in Medicare reimbursement over the next 3 or 4 years. These are hospitals in small towns of 3,000 to 5,000 that are situated at some considerable distance from major metropolitan areas. If you do not have hospitals in those towns, you will not have physicians practicing in those towns and it is a matter of economic survival to those communities. It would be equivalent to losing your school.

So we are not talking just about reductions in the rate of growth. We are talking about actual cuts. For instance, the remuneration for a cataract operation in those hospitals currently is about \$1,300. I think they are scheduled to go down to \$980, as sort of an average.

The University of Iowa, a teaching hospital, is scheduled to lose \$65 million under BBA. It is clear in my mind that we need to make an adjustment for rural hospitals and for the teaching hospitals from BBA.

Just to go back historically, I remember in 1995 the Budget Committee came out with a proposal to cut Medicare by \$285 billion. Mr. Chairman, can you imagine what we would be dealing with today had that become law? And I remember sitting down with the Budget chairman, with the Speaker of the House and many others and saying, "If you do this, you are going to be significantly hurting patient care," and I just could not get anywhere.

So finally, as you well remember, Mr. Chairman, in a hearing of this subcommittee in 1995 I became the first Republican to speak out against that budget as it related to Medicare and if looks could

kill, I would be dead today. But fortunately, we were able to reduce that to \$115 billion and I voted for that bill, but on the proviso to my leadership that we would look at the results of that bill and if necessary, we would come back and do an adjustment.

For 6 months I have been trying to get our leadership in the House to deal with this issue and it does fit into the issue of our total overall budget, whether we are talking about tax cuts or reducing the debt or finishing up our appropriations bills.

And so I am very glad that we are having this hearing. I can tell you that my State of Iowa, the hospitals and the providers are 24th in the country in terms of their overhead. They are 48th in the country in terms of their reimbursement. And if you add BBA to that with consequences that are growing way beyond what we envisioned when we passed the bill, then it is a prescription for some real trouble with patient care that we are going to hear about today.

So I believe that this Congress needs to get a move on on this issue and I look forward to the testimony. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Green for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman, and I would like to, like my colleagues, thank you for scheduling this important hearing and associate myself with the remarks of my colleague Ms. Eshoo and particularly Mr. Greenwood on the all the unintended consequences and the response we have.

When Congress passed the Balanced Budget Act of 1997, the Medicare spending was firing out of control. Something needed to be done to slow the growth and stabilize the Medicare program until a long-term solution could be found. However, the state of Medicare, along with the rest of the Federal budget, has improved much quicker than any of us anticipated. The fact is the Medicare spending rate has been significantly lower than anticipated and while this is good for the long-term stability, I am concerned about the negative impact it is having on the beneficiaries.

Almost since the day it passed, providers have been warning us about the effects the cuts will have. And while much of the BBA is yet to be implemented, we already are seeing some of the worst case scenarios come true.

Home health care agencies around the country are closing, leaving hundreds of counties without any provider. And this week Vencor, which operates nursing homes and hospitals all over the country, including in Pasadena, Texas in my district, filed for bankruptcy. And this may be just the beginning. As the PPS for skilled nursing facilities is fully implemented, there is a widespread concern that the sickest and the most frail beneficiaries will be unable to receive all the care they need once they reach their therapy caps.

And finally I would like to address the potential negative impact the hospital out-patient prospective payment system could have, particularly on patients with cancer. Under the proposed rule, HCFA proposes to bundle the cost of all cancer drugs into a small number of ambulatory payment categories, APCs, and pay hospitals only the average cost of these services. The main problem with this proposal is that it fails to recognize the complexities of

cancer treatments and the wide range of individual needs of each patient with cancer.

As a result, the payment system could threaten the quality and availability of cancer treatment for Medicare beneficiaries. In fact, under HCFA's proposed plan, the lowest reimbursement rate for some cancer treatments would be under \$60, which is expected to include supportive care. Moreover under the proposal, new drugs, which are defined as anything after 1996, would be reimbursed at the lowest rate. This policy would create an overall reduction in the quality of patient care, since hospitals would be pressured to provide the least expensive rather than the most effective treatment.

Moreover, research and development for new drug therapies may be diminished and delayed, ultimately denying the patients of today in those future generations access to more effective treatments. How can HCFA expect hospitals to prescribe the newest and in some cases the most effective drugs, many of which cost hundreds if not thousands of dollars, if they are reimbursed less than \$60?

I have introduced H.R. 1090, the Medicare Full Access to Cancer Treatment Act. This bill already has 55 bipartisan cosponsors and it carves out cancer treatment from the out-patient PPS. This simple yet sensible action would fully protect Medicare beneficiaries' continued access to the best and most effective cancer care.

I know HCFA has received numerous comments on this issue and I hope their final rule makes our legislation unnecessary. However, if their proposal is implemented as originally proposed, the recent advances in cancer treatment and the billions of taxpayer dollars dedicated to finding cures for cancer will be wasted.

Again Mr. Chairman, I thank you for scheduling this hearing and look forward to discussing these issues with our panels.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bryant?

Mr. BRYANT. Thank you, Mr. Chairman.

I, too, as every Member of Congress, not just on this subcommittee, heard during our August recess complaints from hospitals and home health care agencies and nursing homes and I, too, think they are legitimate.

I thank the chairman for convening this hearing. I thank the numerous very competent and qualified people we have here to testify today. And in the interest of somewhat speeding this along, I will yield back my time. Thank you.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Stupak for an opening statement.

Mr. STUPAK. Yes, Mr. Chairman, and thank you for holding this hearing. I, like many of my colleagues, have heard from health care providers about the problems that the Balanced Budget Act of 1997 has been causing them.

I am especially concerned about the effects of the BBA on rural areas. I know my friend Dr. Ganske pointed out some of these things. I think even the administration recognizes this fact. If I can quote Dr. Robert Marinson. He's the director of the Center for Health Plans and Providers of HCFA.

He testified earlier this year and he said, and I quote, "About one in four Medicare beneficiaries live in rural America and rural hos-

pitals serve a critical role in areas where the next nearest hospital may be hours away. Yet rural hospitals face special challenges. They have a higher per unit cost, difficulty maintaining enough patients to break even, and difficulty recruiting physicians. Medicare has made exceptions and special arrangements to address the unique needs of rural areas and strengthen these vital facilities. Even before the BBA, Medicare provided special payment support to more than half of all rural hospitals." That is the end of his quote.

The special challenges and concerns are why the BBA has had a disproportionate impact on rural areas. The administration understands the concerns of rural areas and has proposed a number of steps to begin to remedy these conditions.

As our chairman Mr. Bliley pointed out, he wanted to know some things that could be done. I would ask that he and all of us take a look at the President's Medicare plan, which adjusts the wage index in rural areas, the new out-patient PPS system to increase payments to low-volume rural hospitals, the transition to PPS to allow for a budget-neutral impact, the timeframe for implementing the volume control mechanisms on the system that were called for in the BBA, which also will give hospitals extra time and money to adjust, and finally, increase the rates for in-patient rural hospitals to larger than they would receive under a straight-line extension of the BBA from 203 to 209.

I appreciate the President's proposals and I hope we would all look at them and his desire, the President's desire, to improve rural health. However, I believe that we do need to go further. I would urge HCFA to listen to the rural providers in my district and all around the country about their financial condition. Unlike areas where the country where a number of providers compete to provide health care services, in my district there is only one hospital servicing one or more counties. There is a limited number of nursing homes and home health agencies. If any one of these facilities failed financially, residents may be forced to drive hundreds of miles to the nearest surviving health care facility.

I know many of my providers, and I believe them when they tell me that these cuts, especially to the out-patient department, are injuring and damaging their financial bottom line.

Mr. Chairman, it is crucial for Congress to enact these issues. I support the President's plan to increase funding for rural hospitals. I think it can be improved and I urge my colleagues to sit down and start discussing these issues. We can and we must ensure our constituents have access to affordable health care.

Mr. Chairman, thank you again for holding this hearing. I look forward to working with you. I will be in and out all day as we have an amendment or two on the floor. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Burr for an opening statement.

Mr. BURR. Thank you, Mr. Chairman. Welcome, Mike.

Mr. Chairman, it is evident as I look out at this audience, I see something significantly different than I have seen at health care hearings before. There is a fear in everybody's eyes. It is the same fear that I have seen at hospitals and doctors' office but more im-

portantly, it is the same fear and question mark that exists in the public across the country.

And I think the real challenge and the real answer that we need to find out today is not the short-term and the long-term solutions to these problems but it is a question of can Congress and HCFA work together to, in fact, identify the problems and come up with real solutions that address them for the short-term benefit and for the long-term benefit?

Short term, we have some financial crises that have to be addressed. They will be addressed hopefully through legislation that we, in a cooperative way, try to address before the end of this calendar year. And it will enable providers to deliver care that we would consider to be basic care in many cases.

But I think that there is a long-term crisis that many of us do not have on our chart yet. That long-term crisis is the way that financial markets look at the health care industry today, look at providers all across this country and the fear that they have to make an investment. Somebody, I think Mr. Green, alluded to Vencor's most recent problems. Vencor is not the first and they will not be the last to experience the shortage of capital needs to meet current debt but in their particular case, they can no longer think about future needs.

Mr. Chairman, we have to be as concerned with today's crisis as we are with tomorrow's needs. And I think for that reason I am hopeful that this will be the start of a process that brings not only the short-term benefits that are needed within this industry but also some sense of confidence that long-term, this will be predictable. And I think that we both share blame, HCFA and Congress, about the unpredictability of, in fact, where we are.

Mr. Chairman, this is an opportunity to get the policy right if, and I say that in a big way, if we can keep politics out of this issue. I am confident with the efforts that I have seen from HCFA, with the work that I have seen from my friends on the other side of the aisle but, more importantly, the interests of the American people, that we will keep politics out of it and we will, in fact, find the right balance.

Mr. Chairman, every member on this committee probably has one special interest that they have been counseled aggressively over the August break, whether it is a hospital or a long-term care facility, whether it is a specific service, and they all have merit. There is no question.

I am hopeful that this committee and HCFA will understand that we cannot respond to every need tomorrow, but our job is like it was 2 years ago when we started on this, to try to find the right balance. I have always suggested, since I have been in Congress, never to judge Members of Congress on what we did but to judge us on our ability to identify our mistakes and how quickly we go and fix them.

We work within the confines of a lot of different constraints. I am confident that we can design a better delivery system, one that fairly reimburses, one that delivers the same quality of care that we are all after. But I would challenge my friends on this committee that it will demand a tremendous amount of work in the next several months to start that process and to hold the type of

control that we need to make sure that we do not end up with the same product that we started with several years ago.

I thank the chairman and I yield back.

Mr. BILIRAKIS. I thank the gentleman. Well said.

Ms. Capps?

Ms. CAPPS. Thank you, Mr. Chairman, for holding this very important hearing.

The Balanced Budget Act of 1997 enacted some far-reaching changes in the way Medicare pays health care providers. These changes were intended to both modernize Medicare and save some \$115 billion over 5 years.

Today there is growing debate about whether the savings are actually much larger than Congress had anticipated and how those changes could be affecting services. The provider groups say that they are larger than expected and that delivery of care could be compromised. MedPAC, GAO and HCFA seem to be saying it is too early to tell but that we should be watchful.

Like so many members, I have been hearing some health care providers in my district regarding these cuts in the BBA and how they are affecting and may affect in the future the ability of providers to provide quality health care to our seniors and to others in our communities and I take these concerns very seriously.

There are a number of issues which I hope the subcommittee can explore this morning and I really stress the timeliness of this hearing and thank the leadership for providing it. For example, according to MedPAC, the cuts to hospitals are expected to have the most dramatic effect in small, rural hospitals and cancer hospitals and my colleagues Green and Stupak have addressed these issues and I underscore their comments in this area. I want to hear from HCFA what steps it plans on taking to ensure the viability of these critically important institutions.

I also would like to explore the effects of the \$1,500 therapy cap. Are beneficiaries losing access to critical care under the cap? And if so, is this what the intention of the cap was?

And that is what this hearing is really all about. How are these changes affecting the delivery of care to seniors and others in our communities? I am heartened by the fact that many we have checked with seem to be saying that quality of care has not been affected yet, but I am also very worried because I know, as you all know, that the most dramatic changes are still to come.

I am also concerned that the numbers we are seeing are not reflecting the whole story, that if we have shorter numbers of days in hospitals, if we have fewer home health care visits, does this really mean that we have healthier citizens? I do not think it necessarily does translate that way and that is why I am concerned about the numbers.

And that is why I am particularly looking forward to our witnesses today on these and other critical issues and I particularly look forward to panel three when we can hear from people who are

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I want to pay special attention to what, for example, Roberts will be saying from Kent County Visiting in Rhode Island. Earlier in my career I was a resident in New Haven, Connecticut and I trust that these provisions on real health care in our country today.

And I want to make sure that when we talk about marketplace numbers and how this translates that we do not forget that it is patients and people receiving care that are the bottom line of what our business of health care is all about. And I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentlelady.

Dr. Norwood, an opening statement?

Mr. NORWOOD. Thank you very much, Mr. Chairman. I will submit for the record but let me just briefly say that we have for a long time tried to understand how to pay for a government-run health care system, which basically Medicare is, and the American people clearly want all of the health care we possibly can afford them and Congress seems to want to give them all of the health care that they want. It is a continuing and ongoing problem, however, as to how to pay for that.

Now some of us who have a bias, such as myself, want to put money into health care. However, I do not want to do so to the extent that my grandchildren pay for the benefits that patients today receive. And part of our problem is in prioritizing our expenditures is that if you want to put more into the Medicare system, you have to find somewhere else to take the money out because there is a limitation on the number of funds.

Now I have heard 2 or 3 members here act so surprised that providers are dropping out of Medicare Plus. Well, of course they are dropping out of Medicare Plus. It is a very simple principle. When you will not pay people the cost of doing business, they go out of business. They cannot continue in a program where they continually take a loss, particularly in this day of managed care where there is not that old cost-shifting going on because that is not possible anymore.

We look at our rural hospitals and we wonder what is happening. Well, of course they are going to close. Medicare and Medicaid are the only thing most of them can depend on because they are never one of the discounted hospitals in managed care. They never do anymore have patients coming into their hospitals that have good insurance plans, indemnity plans or fee-for-service. They are dependent on Medicare and Medicaid.

Well, if you are not going to pay them the cost or less than cost, which is exactly what we are doing, they are going to close.

Our teaching hospitals are in a great deal of trouble in terms of the lack of dollars that are going to the teaching hospitals and you are going to find that we are going to suffer greatly in the 21st century if we allow our teaching hospitals to continue to go down because we cannot cut funds somewhere else to put it into this vital issue of health care.

And I would say to you, you wonder why home care agencies are closing in your district? Of course they are closing. We will not pay them the cost of being in business and they cannot cost-shift anymore.

So Mr. Chairman, the question here is in my mind, do we need to put more money into this? Yes, we do. Do we need to offset that spending somewhere else so we do not charge this ticket to our grandchildren? Yes, we do. And it would be very helpful if, on a bipartisan basis, we would be willing to prioritize our spending and

recognize as a Congress that we have to take this out of other places if we think health care is a vital interest to the people of this country, which I am fairly sure, listening to the members here today, they were told while they were home on August break that yes, it is a vital interest and no, we do not want our home health closing; no, we do not want our rural hospital closing.

We are disappointed that providers are dropping out of Medicare Plus and the answer is not real difficult. We have overdone it. We need to put more money back into it. And, by the same token, we do not need to go back to years gone by and keep adding to the \$5.5 trillion debt to push this.

So I hope the members on the other side of the aisle, and they seem to say so, recognize the importance of this and the importance of determining where else in this large Federal budget we must slow down spending there in order to get the spending level back to the right level in health care.

With that, Mr. Chairman, I will yield back and I thank you very much for this hearing.

Mr. BILIRAKIS. I thank Dr. Norwood.

Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. Mr. Chairman, I think this hearing today is really timely and I appreciate you holding it. I think that the Balanced Budget Act needs to be examined to see if it is achieving its intended results in a lot of areas and I have a couple of specific examples of areas that I want to talk about today.

I think that the substantive policy changes implemented have resulted in significant savings and in many ways have streamlined both Medicare and Medicaid in positive ways. For example, the Medicare Trust Fund has been strengthened and also as co-chair of the Congressional Diabetes Caucus, I point to the positive step of the implementation of critical preventative health benefits like coverage for blood glucose test strips for diabetes.

However, the frugality that we have achieved only helps beneficiaries if it is coupled with policies that ensure those beneficiaries to have access to the necessary care in the appropriate setting. And I am hoping today's hearing will shed some light on the reforms that have helped beneficiary care and which ones are hurting the very people that they are intended to help.

And let me give you an example. In an effort to tighten eligibility rules for home health care, I am concerned that HCFA has unintentionally prevented beneficiaries from accessing the services they need. I have a constituent, for example, who has gone blind from diabetes. Well, we will give her the blood glucose test strips but the problem is since she is blind, she cannot measure out the correct dosage of her insulin to prevent further onset of the complications of the disease.

Now she used to have her home health visits covered by Medicare when someone came once a week to fill the insulin syringes that she would need for the whole week. But because that is the only service she needs—she does not need blood drawn; she does not need tests done—Medicare no longer covers these visits.

And so we are really not doing much by denying this benefit to help this constituent improve her health and keep it solid as we go along.

The other issue, which several other members have alluded to, is that the Medicare and Medicaid savings for hospital costs have been greater than anyone predicted, which has particularly impacted our Nation's critical safety nets, like the graduate medical education program and disproportionate share hospitals.

As a result of these dramatic cuts in payments, hospitals nationwide are reeling and hospitals in my district are the same as in Congresswoman Capps' and many other districts. University Hospital, Colorado's public teaching hospital, has seen a \$6 million loss of revenue this year alone and these losses are only predicted to grow.

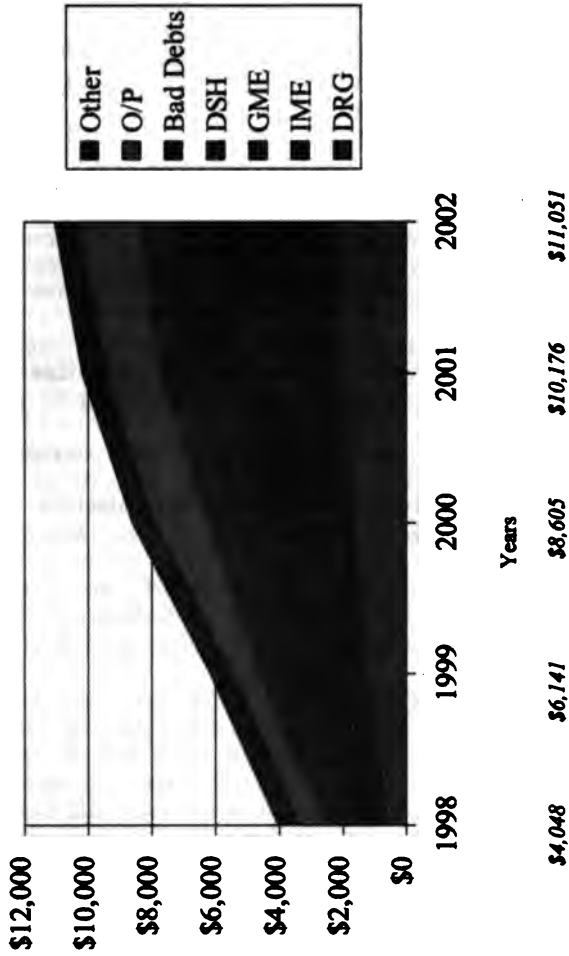
Coincidentally, they were in talking to me about this yesterday, Mr. Chairman, and they provided me with this chart which dramatically shows how these losses are going to grow through the year 2002.

Mr. Chairman, I would ask unanimous consent to include this chart for the record, if possible.

Mr. BILIRAKIS. By all means, without objection.

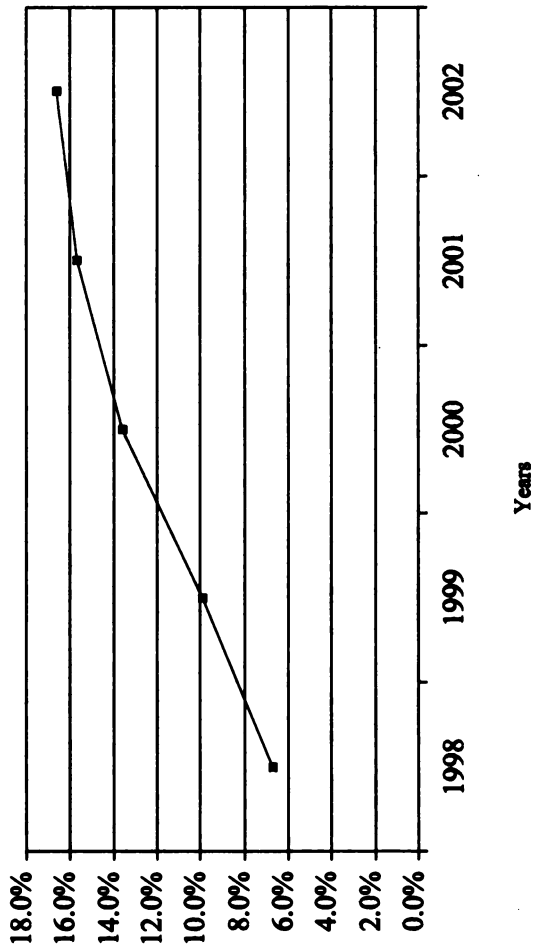
[The chart follows:]

***University of Colorado Hospital
Estimated Medicare Loss for Key Items due to the BBA
(high end of range in 000's)***



Amounts in italics represent the estimated annual BBA impact.

***University of Colorado Hospital
Estimated Medicare Loss for Key Items due to the BBA
as a % of Net Medicare Revenue***



University of Colorado Hospital
Estimated Medicare Revenue Loss for Key Items
Due to the Balanced Budget Act of 1997

	Effect for FY 1996	Effect for FY 1996	Effect for FY 1996	Effect for FY 1996	Effect for FY 1996
DRG Payments	(\$115,000) to (\$520,000)	(\$1,200,000) to (\$1,240,000)	(\$1,200,000) to (\$1,240,000)	(\$1,200,000) to (\$1,240,000)	(\$2,340,000) to (\$2,340,000)
Indirect Medical Materials (IMM)	(\$1,200,000) to (\$1,200,000)	(\$1,200,000) to (\$1,200,000)	(\$1,200,000) to (\$1,200,000)	(\$1,200,000) to (\$1,200,000)	(\$2,340,000) to (\$2,340,000)
Outpatient Medical Materials (OMM)	to to	to to	to to	to to	to to
Disproportionate Share Hospitals (DSH)	(\$200,000) to (\$210,000)	(\$300,000) to (\$310,000)	(\$300,000) to (\$310,000)	(\$300,000) to (\$310,000)	(\$230,000) to (\$230,000)
Bad Debt	(\$420,000) to (\$430,000)	(\$400,000) to (\$410,000)	(\$400,000) to (\$410,000)	(\$400,000) to (\$410,000)	(\$925,000) to (\$925,000)
Outpatient (ANCs)	(\$200,000) to (\$200,000)	(\$200,000) to (\$200,000)	(\$200,000) to (\$200,000)	(\$200,000) to (\$200,000)	(\$1,000,000) to (\$1,000,000)
Other	(\$100,000) to (\$100,000)	(\$100,000) to (\$100,000)	(\$100,000) to (\$100,000)	(\$100,000) to (\$100,000)	(\$1,000,000) to (\$1,000,000)
Total	(\$3,790,000) to (\$4,040,000)	(\$3,800,000) to (\$4,040,000)	(\$3,800,000) to (\$4,040,000)	(\$3,800,000) to (\$4,040,000)	(\$11,890,000) to (\$11,890,000)

Notes: Above data was calculated using a BSA Impact Worksheet provided by AMA.
Medicare revenue loss is estimated for the years 1996-2002, which is the five-year period the BSA addresses.

1/

2/ Other includes Indirect Capital and the Hatch Unit.

DRG Payments - Disproportionate Share Hospitals (DSH) payments are a net amount per discharge. Each DRG assumes an average length of stay.

IMM Payments - Indirect Medical Materials (IMM) payments are additional payments made to teaching hospitals to recognize their higher cost of hospital care when compared to non-teaching hospitals.

OMM Payments - Outpatient Medical Materials (OMM) payments are paid to hospitals that treat outpatients in an approved ambulatory program.

DSH Payments - Disproportionate Share Hospitals (DSH) payments are paid to hospitals that treat a disproportionately large number of low-income patients.

Bad Debt - Medicare beneficiaries are responsible for their deductible under reimbursement. If other current collection procedures this amount is written off as a bad debt, the hospital can then obtain this amount on the Medicare Cost Report.

BSA Analysis for DRG

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Ms. DEGETTE. Now University Hospital is putting a plan in place to reduce the number of resident positions, which will impact the future number of doctors we have in Colorado just as our population is growing. And then, as a result of that cutback, the hospital is being forced to cap indigent care, which is a step in the wrong direction at a time when the uninsured numbers are growing at an unprecedented rate.

And so I think these are some of the results of the balanced budget agreement that have to be reversed.

Mr. Chairman, because of my deep concern about these issues and because of the need to protect the Nation's safety nets, I am going to be introducing legislation called the Medicaid Safety Net Preservation Act of 1999. This legislation recognizes that if we make further cuts to the safety hospitals, we are going to have terrible problems.

In the State of Florida, safety net hospitals like Jackson Memorial in Miami and Tampa General Hospital in Tampa are facing an 18.8 percent reduction in Medicaid DSH payments between fiscal year 2000 and 2002.

The bill I am introducing would freeze Medicaid DSH payments at the fiscal year 2000 level through 2002 to ensure that the hospitals who serve our most vulnerable populations may continue to do so. This is only a stop-gap measure and I am hoping that we can look more broadly, Mr. Chairman, on equalizing these disproportionate impacts as we move forward into the next millennium.

Thank you and I will yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentlelady.

Mr. DEAL for an opening statement.

Mr. DEAL. Thank you, Mr. Chairman.

I have reviewed the statements here today, I have listened to the opening statements, and there appears to be one missing ingredient that has not been addressed and I hope that the panelists will do so. That is the motivation for the Balanced Budget Act changes that we made.

My recollection is that the reason that we did that was that for 30 years since 1965, when Medicare went into place, the system of FICA withholdings into the trust fund had been sufficient and, in fact, had accumulated a surplus. And then, at the end of that 30-year period, suddenly the process began to reverse itself to the point that in 1997, my recollection is that the Medicare Trust Fund was expending something in the neighborhood of \$40 million more every day than it was taking in from the FICA tax, which was its sole funding source for Medicare Part A, and that that was the motivation for these changes.

Therefore, if that is the motivation, I think we ought to ask the question: What will the proposals that we are going to hear today do in terms of impacting the financial solvency of the Medicare Trust Fund? We were told in 1997 it had a life expectancy of only about 4 years and without significant changes, maybe even shorter than that.

So to talk about proposals to the Balanced Budget Act changes without understanding the reason for those changes to begin with and without answering the question of what will these new pro-

posals do in terms of the solvency of the Medicare Trust Fund, I think is being disingenuous. It is not addressing the real concern here.

Now if we are going to continue to move in the direction of moving proposals out of Medicare Part A into Part B, as we did with home health care, then we run into the continued criticism that we are moving it from a dedicated revenue source as its sole funding source into more of a welfare system, and everybody says we do not want to move in that direction.

So if that is not where we want to go, then what are we going to do in terms of the financial solvency of Medicare, the trust fund and where is that trust fund right now in terms of is it still continuing to lose, which I think it is, continuing to drain the trust fund even now, and if we make changes to the Balanced Budget Act provisions, will it accelerate that continued draining of the trust fund, and what then will be the life expectancy of that trust fund with these proposals? I think that is a challenge that we all have to face and if we do not understand that as the premise that underlies what was done in 1997, then I think we have missed the point.

Mr. Chairman, I hate to make an opening statement that seems somewhat confrontational and then have to leave but I do have a mark-up in another committee, but I will be back. Thank you.

Mr. BILIRAKIS. Thank you, Mr. Deal.

Mr. Barrett for an opening statement.

Mr. BARRETT. Thank you, Mr. Chairman.

Like many other members of the committee, during the August recess I met with providers in my district, virtually all of whom obviously were unhappy with the direction that we are headed and are very concerned about the impact of the Balanced Budget Act on them. I heard from physical therapists; I heard for occupational therapists, home health care providers, nursing home executives, hospital executives and physicians.

Every single group that I talked to, I had to bring in sort of the subject du jour, which is also the subject today of President Clinton's action, and that is the tax bill, the \$792 billion tax cut. And as I explained to each and every one of those groups, they were, in fact, paying for this tax cut proposal because just like Willie Sutton robbed banks because that is where the money was, a lot of the cuts are coming in health care because that is where the money is.

So for us to sit here today and say well, this is a problem; we have to make cuts in other areas, makes me question what planet I am on because I know earlier this year we as a Congress decided well, we do not want to make cuts in defense spending; we will spend more money in defense spending than we agreed to in the Balanced Budget Amendments. We do not want to make cuts in transportation; in fact, we will spend more money than we agreed to in the Balanced Budget Act.

So we are going to have these magical cuts that are going to occur and that are going to allow us to make everybody in this room happy. I do not think everybody in this room is stupid and I think people recognize that if we are going to provide relief for health care providers, that means that we are going to have to make some basic changes here. That means all this talk about a

tax cut is pure folly because we do not have a surplus right now. In fact, with the spending that we have done on the census, on the emergency spending bills, on defense, on transportation, we have basically gotten rid of the surplus for this year.

So we are dealing with a situation now where we are going to have to decide whether we are going to pose for political holy pictures or whether we are going to deal with health care in a serious way. And it is my hope that we are going to be able to work together to fashion some relief for those who need care; for example, those who have come up against the \$1,500 cap, to make sure that people are not hamstrung when they are moving from a hospital to a nursing home. And I think to do that is going to take some honest discussion, not only by this panel and this committee but by all of Congress.

So I hope we are up to that task because I think that this issue is far too important not just to providers—providers are big boys and girls and they can basically lobby for themselves and take care of themselves but I am concerned about that person who is confined in a home and has someone who comes in to give them home care and is not going to be able to receive that home care because of the actions that this Congress has taken over the last several years.

I hope we have a productive hearing today and with that, I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman.

Mr. SHADEGG for an opening statement.

Mr. SHADEGG. Thank you, Mr. Chairman. I want to commend you for holding this extremely important hearing.

Although I think in opening statements we are quickly approaching the point where everything has been said but not everyone has said it, let me briefly comment that I too, like many of my colleagues, went home over the August break and met with various providers—hospital operators, home health care operators, nursing home facility operators—and heard poignant stories about the difficulties they are facing.

We clearly have to look at the circumstances that BBA 1997 has created and the numbers speak for themselves. They show that we have achieved a level of reduction in spending far beyond that which we originally anticipated. So I commend you for holding these hearings.

I would like to associate myself with the remarks of Mr. Greenwood, who said that if, in fact, we overreacted in BBA 1997, I hope we do not sit here 2 years from now in 2001 and say we then overreacted to that overreaction in 1999.

So I think it is very important that we strike a balance. I think it is critically important that we ensure that the funds are there to provide the necessary care for those in America's facilities and that we ensure that those that operate them have the financial incentive to continue to do so, and that is an obligation that we owe to the American people. I think it is a fiduciary obligation that we owe to the American people.

I look forward to hearing the testimony of the witnesses and to their educating us as to how we can best solve this problem and

strike what would be an appropriate balance for providing the kind of health care that needs to be provided.

And with that, Mr. Chairman, I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bilbray.

Mr. BILBRAY. Mr. Chairman, I was not planning on giving an opening statement but I just want to say, as someone who has had the privilege, and I think that Ms. Eshoo of California probably did, too, or the challenge of operating public facilities, nursing homes, I would just ask us all to consider the fact that this is not a Democrat or Republican issue.

And I just ask my colleagues, we talk about tax reduction and tax fairness and the other side can turn around and say every time the administration goes on a trip they promise another \$100 million for somebody. We can use this as a vehicle to beat and bash at each other for political advantage, but I think it is totally not only inappropriate; I think it is immoral when we talk about we care about this crisis but then we are going to take the time to take a shot across the aisle.

And I would ask us not to do that. We are in this together. Like it or not, we are going to be judged by the American people together, Democrat or Republican. And I think the challenge here is to find answers rather than finding fault, and let's move forward.

I yield back, Mr. Chairman.

Mr. BILIRAKIS. Thank you. Mrs. Cubin.

Mrs. CUBIN. Thank you, Mr. Chairman, and thank you for holding this hearing today.

Undoubtedly we all have heard the same information. In fact, obviously we have all heard the same information when we went home and came back with a message from our constituents and from our health care providers that simply it is not working.

I think anyone who thought that the Balanced Budget Amendment would be just fine as it was, that it would not need some fine-tuning and would not need some adjustment was naive. And hopefully we will hear from you how we can make some of those adjustments to solve some of the problems that all of us are aware of.

The Balanced Budget Amendment, as we all know, was designed to save money within the Medicare program by slowing the rate of growth in payments to hospitals and health care providers, physicians, and so on, and by establishing new payment methodologies. And while Medicare has saved money as a result of the BBA, it has also caused some of what I truly believe to be unintended consequences that are quite negative.

I have heard from so many people in my home State about the financial burden that has been placed on physicians, hospitals and health agencies and I want you to understand something about my State. It is almost 100,000 square miles. It takes 8½ to 9 hours to drive from corner to corner in my State. The largest city is 60,000 people. There is another city of 50,000 and then it drops down to one city of 20,000 and then 12,000 and then 3,000, 150.

So when I tell you that what is happening with the reimbursement schedule and the reimbursement practices now will close the only health care facilities that there are in communities for hun-

dreds of miles around, I am not exaggerating. So we have to do something to stop this.

Now that brings me to another thing that I will be asking and hoping I can get some information on today and that is I want someone to justify for me the difference in the reimbursement. For example, a regular routine office visit in Wyoming paid to a physician, the reimbursement is approximately \$33. In New York it is \$64. A regular routine EKG in Wyoming, the reimbursement is \$20; in New York, \$47.

I use New York because I did not have time to get Florida, Pennsylvania and other highly populated areas, also California.

Gall bladder removal in Wyoming, \$461; \$601 in New York. Colonoscopy, \$199 in Wyoming, \$301 in New York.

Now this is part of the problem that is causing Wyoming health care providers to leave the State, to close the institutions that we have.

So in addition to dealing with the methodology, I want someone to explain to me why these reimbursements are so different, especially when you take into consideration the average price home in Jackson Hole, Wyoming is \$657,000 and the commercial property is proportionately as high. Residences are proportionately as high.

When students graduate from medical school they have the same loans that they have to pay back. The equipment costs the same to them, no matter where they practice. They have to pay employees. The costs are not that different. Please somebody explain to me why there is such a huge discrepancy in these reimbursement levels.

Truly these effects and the effects of the BBA are having a disastrous effect on Wyoming.

I am also concerned, as is Congresswoman Capps, about the \$1,500 cap on rehabilitation services. As a patient who received extensive physical therapy myself and only because of that am I walking today, I know that \$1,500 can be used up in a month or less.

So I look forward to understanding why some of these things are being promoted and I thank the chairman for having the hearing today.

[The prepared statement of Hon. Barbara Cubin follows:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF WYOMING

I would like to thank Chairman Bilirakis for holding this educational hearing on the implications of the Balanced Budget Act of 1997. Anyone who thought the BBA would not need fine tuning and adjustment was naive. Hopefully, we will hear how to make some of those adjustments during our discussion today.

I have heard from so many people all across my home state of Wyoming regarding the extreme financial burden placed on physicians, hospitals and home health agencies because of the BBA. While Medicare has saved money as a result of the BBA, it has also produced, what I truly believe to be, unintended consequences.

Let me tell you a little about my state of Wyoming and how the health care system works in a rural area. It takes 8 to 9 hours to travel from one corner of the state to another. There are hospitals of minimal size that are hundreds of miles apart that have to serve a population of 250,000. The few doctors we have serve many Medicare patients without receiving adequate reimbursement, and are coming dangerously close to being forced to opt out of the Medicare program. For example, the reimbursement rate for a regular office visit in Wyoming is \$33 but in New York it is \$64; for an EKG in Wyoming it is \$20 but in New York it is \$47; for a gall-

bladder removal in Wyoming it is \$461 but in New York it is \$601. Can somebody please explain to me why that is?

So I'm not exaggerating when I say that this has truly devastating effects on a rural state like Wyoming that has very different health care needs. We cannot afford to have health agencies closing and Medicare beneficiaries losing their providers because Wyoming does not have an abundance of these health care services.

I'm also concerned about the \$1500 annual cap on rehabilitation services. Patients can easily exhaust this sum on routine therapy in a few months, and the rest of the year these poor patients are struggling to make ends meet. Often times, they even have to forgo therapy because they can't afford it.

I really would like to understand this reimbursement schedule, but I also know that many people simply do not realize that these rates and these cuts are very disproportionate between rural and urban communities.

I look forward to hearing your comments in this regard. Thank you.

Mr. BILIRAKIS. I thank the gentlelady.

I believe that all of the opening statements finally have been completed.

Mr. Brown?

Mr. BROWN. Mr. Chairman, can I ask unanimous consent to enter Mr. Dingell's comments in the record and any other member that has additional comments?

Mr. BILIRAKIS. Without objection, that will be the case.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding today's hearing. The Balanced Budget Act made the most sweeping changes in the Medicare program since its inception. It is vital that we in Congress closely monitor those changes and their impact on beneficiaries' access to care and the quality of care they are receiving.

In a sense, the Balanced Budget Act completed—or at least brought closer to completion—work Congress began back in 1983 with the enactment of a prospective payment system for Medicare hospital reimbursement. At that time, we were facing a crisis. The Medicare hospital trust fund was being drained dry by double-digit growth in spending. We had to act to save it. When we looked at the roots of the crisis, we realized that the way we were paying for hospital services was a very large part of the problem. We were paying on a per-service basis—the more admissions, the more services, and the longer the stay, the higher the reimbursement. We replaced this inherently inflationary system that did nothing to encourage efficiency with a prospective payment system. It took a lot of getting used to, on the part of hospitals and beneficiaries alike. It needed some adjustments, particularly for rural providers. And we also found out rather quickly that we needed to have in place a system to ensure that beneficiaries weren't being discharged prematurely or otherwise receiving less-than-appropriate, high-quality care. But the system fundamentally worked. We were "buying a lot smarter" when it came to inpatient care, and the trust fund crisis was averted.

In 1997, we were again facing a crisis. The trust fund was again racing toward empty. Home health care, skilled nursing care, and outpatient costs were exploding. We had to act to rein in these costs—and to address one of the major factors fueling this explosion—again, cost-based reimbursement systems that rewarded over-utilization and outright fraud and abuse. We replaced these with prospective systems, which are now being phased in, and some interim provisions until the systems were fully operational.

I think we did the right thing in 1997. But just as we learned in the 1980s as the hospital prospective payment system was implemented, we need to be very vigilant in ensuring that these new systems do not adversely affect beneficiaries' access to care and the quality of the care they receive. And that means being sensitive, as well, to what Medicare hospitals, nursing homes, home health agencies, therapists, and others are telling us about the impact the new systems are having on them. We need to be open to suggestions for refinements.

PREPARED STATEMENT OF HON. TED STRICKLAND, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF OHIO

Mr. Chairman, I want to thank you for convening this hearing today so that we might learn more about the effects of the Balanced Budget Act of 1997 on patient care and access. I am sure that every Member of Congress has heard concerns about the BBA from constituents and health care providers.

In my rural Ohio district, which is medically underserved, access to adequate care is a great concern. In the past year, the communities I represent have lost ground in their struggle to provide care, especially for those with little or no insurance. Home health agencies have closed and one of the largest communities in southern Ohio has lost the supervising physician who provided family practice care for the uninsured and underinsured. The rural health clinics are fearing that they will have to use the grant funds that are intended to help them treat the uninsured to make up for the losses in Medicaid reimbursements. I have visited with each of the hospital administrators in my district, who tell me that their hospitals are losing money at such an alarming rate that they will soon be forced to reduce services like hospice, home health care and skilled nursing care. Many of these hardships are a direct result of changes made in the Balanced Budget Act of 1997, including caps on DSH payments and the implementation of the inpatient and outpatient prospective payment systems.

Clearly, the hospitals, clinics and home health agencies in my district are being affected by changes that are not part of the Medicare fee-for-service program. In addition to fee-for-service changes, they are adjusting for the BBA's changes to Medicare+Choice and Medicaid. So the emergencies in funding they face in many cases cannot be traced to a single change in statute. Rather it is the confluence of BBA changes that is forcing health care providers to reduce services or close their doors.

In rural areas like southern Ohio, the loss of a single provider can be devastating to the community. Our duty is to work with HCFA to provide relief to these providers so that they can continue to care for our constituents in an adequate and efficient manner. This relief needs to be delivered quickly, before we see an even greater drop off in services and providers.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

I am pleased that Chairman Bilirakis has called this hearing to assess the overall effects of the 1997 Balanced Budget Act on the Medicare program and patient care. In 1997, the Republican-led Congress cut \$115 billion from the Medicare program and made substantial changes in provider payment policies to do so. While all of the provisions in the Balanced Budget Act are not yet fully implemented, the Health Care Financing Administration has done a commendable job in implementing the more than half of the 300 or so provisions that we passed two years ago.

At this juncture in implementation many of us are hearing complaints about certain provisions in the BBA. Some of the BBA policies were necessary improvements in the program to improve beneficiary care, and some were initiatives to reduce fraud and abuse. However, in some areas, the BBA may be having unintended adverse consequences for the Medicare program. Changes of such great magnitude do not come easily, without some degree of market upheaval and complications for those involved.

I have heard a great many protestations from provider organizations, and good friends in the provider community back home, that the Balanced Budget Act is having unintended effects on their ability to continue to serve seniors and maintain a viable practice. I am very concerned about these reports, and I am pleased to see that this Committee is taking an opportunity to explore some of these issues. Because we must preserve the integrity of the Medicare program for those who depend on it, America's seniors and disabled, the Committee should hear from beneficiary groups on this matter in the future.

This hearing is a first step in identifying potential problems that could have a negative impact on patient care. As a Congress, we must work together in a bipartisan manner to rectify any troublesome issues that arise.

I welcome the testimony of today's witnesses and I look forward to future Committee action on this topic.

Mr. BILIRAKIS. Panel one consists of Mr. Mike Hash, Deputy Administrator and Acting Administrator of Health Care Financing Administration.

Michael, you have always been considered a member of this family up here as you worked on this committee for quite some time. You have sat there and heard all these opening statements. I know we are all on pins and needles just awaiting your responses to all of these.

Please proceed, sir. You have 10 minutes.

**STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR,
HEALTH CARE FINANCING ADMINISTRATION**

Mr. HASH. Thank you, Mr. Chairman. Chairman Bilirakis, Congressman Brown and distinguished members of the Health and Environment Subcommittee, I want to thank you for inviting us to this very critical and important hearing and for the careful and thoughtful considerations that have been a part of everyone's opening statements.

While I was not at home in your districts during the month of August, I, too, heard the same messages that you have been hearing because many of the folks that you have been hearing from have been coming to see us and importantly, sharing their concerns and experiences with the BBA and that is a significant part of the effort to evaluate all that we have tried to undertake.

As you all know, the BBA includes reforms that are critical to strengthening and protecting the Medicare program for the future, including, of course, as has been noted, important new preventive benefits and important changes in the way in which we pay for services under the Medicare program.

But with changes of the magnitude of those included in the BBA, some adjustments are clearly inevitable. We are concerned about the reports concerning the BBA changes, particularly as they may be related to problems of access or quality of care with respect to the services to which Medicare beneficiaries are entitled. That is why we have established a comprehensive plan to work with providers, beneficiaries and with the Congress to monitor the impact of the BBA.

The President has acknowledged that the BBA also went too far and that is, in large part, the basis of his comprehensive Medicare reform plan that specifically has set aside a quality assurance fund in the amount of \$7.5 billion over 10 years to smooth out the changes in the BBA in the remaining years that the BBA is effective for the purpose of ensuring that quality and access to Medicare services is not compromised.

We are working with the Congress and others to identify appropriate and prudent legislative solutions. We have also taken a series, and some of you have alluded to this—Mr. Stupak, I believe, and others—that we have taken a series of administrative actions on our own initiative to help hospitals, home health agencies and other providers adjust to the changes that came along with the BBA.

For example, we have delayed the extension of the hospital inpatient transfer policy beyond the 10 DRGs that were required in the BBA for an additional 2 years.

Second, we are considering, in our regulatory work, delaying the volume control mechanism that again was included in the BBA with respect to the new hospital outpatient prospective payment system for the first few years of that system. We are further considering a 3-year transition to the new hospital outpatient payment system by making budget-neutral adjustments to increase payments to hospitals that otherwise would receive large payment reductions.

And let me just say, parenthetically, we have looked at the impact data as well and we recognize that low-volume rural hospitals, low-volume urban hospitals, teaching hospitals and cancer hospitals are projected, under our proposed rule for hospital outpatient payments to be significantly affected.

We are also proposing to use the same wage index that we now use for calculating or adjusting the inpatient PPS rates for the outpatient prospective payment rate.

Finally, we are, I think, making it easier—that is our intention certainly—for rural hospitals, whose payments are now based on lower rural area average wages, to be qualified for reassignment to areas where they can benefit from a wage index in an adjacent metropolitan area and thus get higher reimbursements under the Medicare program.

Finally, we also have tried to provide some assistance within our discretion for home health agencies. We have increased the terms of our extended repayment plans for home health agencies that have incurred overpayments. We have, in fact, for home health agencies delayed implementation of the surety bond requirement and have modified that requirement to be based not on 15 percent of their Medicare revenues but, rather, a flat \$50,000 surety bond.

And, finally, with respect to home health agencies, we have, with our discretion, eliminated a procedure that we refer to as “sequential billing,” which was an approach we took in order to be sure that we were properly allocating Part A and Part B expenditures for home health, given the changes the BBA made by shifting some of the coverage from Part A to Part B.

But as a result of that sequential billing policy, we believe many home health agencies experienced cash-flow problems and therefore as of July 1, that sequential billing policy is no longer in place. And we have delayed the implementation of another BBA provision relating to the reporting of home health visits in 15-minute increments, again recognizing that new systems and new requirements to actually do this, on the part of home health agencies, need to be taken into account. So, we are taking a slower approach to that.

And obviously we are continuing to look for further opportunities to exercise discretion within the intent and certainly the letter of the law in the BBA.

And with respect to our monitoring efforts, as you all know and you can see from our prepared testimony, we have been working with the General Accounting Office and with our own Inspector General at HHS and with MedPAC and others to gather information about BBA impacts, particularly with respect to an issue that has been mentioned here a lot today, the impact of the BBA limitations on the provision of outpatient rehabilitation therapy services, the \$1,500 cap.

Several reports that we have assembled have indicated that the therapy caps have not allowed Medicare beneficiaries with multiple sclerosis or strokes or certain other serious diagnoses to get the care that they need in terms of rehabilitation therapy services.

There are also issues with respect to the BBA impact on skilled nursing facility payment, particularly in the case of patients that we refer to as high-acuity patients, those patients who require a significant and above-average level of services to meet their health care needs.

We are conducting research on how we can refine the prospective payment system for skilled nursing facilities in a way that patients who fall into the high-acuity category, that the payments for them will be enough to ensure that they are getting the kind of care their condition requires.

Obviously we are continuing our monitoring efforts. I think it is fair to say that none of us is happy with the extent of data that we have about what is really going on currently in the health care provider world. Most of our data sources, in fact, lag significantly. So, it is difficult in the short-term to get a comprehensive assessment of exactly what the financial impacts are in the current time-frame.

But we are, and I want to underscore this, we are anxious and ready to sit down with you and your staffs and with other Members of Congress to begin developing specific proposals as part of a comprehensive Medicare reform proposal, as the President has put forward. This would include, as a part of, I think, our consideration of smoothing out the BBA, dealing with the long-term financial solvency of the Medicare program and, in our view, that means dedicating a substantial portion of the estimated surplus to the Medicare program and importantly, adding a much-needed, very important prescription drug benefit to the basic Medicare benefit package.

And frankly, it is hard to see, in our judgment, where the necessary resources would come from to adjust the kinds of BBA provisions that we have been talking about this morning without a comprehensive reform such as that put forward by the President.

Mr. Chairman, we look forward to working with you in the cooperative bipartisan spirit that many of the members of your subcommittee have expressed this morning. I thank you for holding this hearing and giving us the opportunity to join with you in exploring these important issues. I can assure you that we will be paying careful attention and taking close notes with respect to the kinds of concerns that are raised by subsequent witnesses before you today. Thank you and I would be happy to respond to any questions you and other members of the committee may have.

[The prepared statement of Michael Hash follows:]

PREPARED STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Congressman Brown, distinguished Subcommittee members, thank you for inviting us to discuss possible necessary adjustments to the Balanced Budget Act Medicare fee-for-service reforms. The BBA includes important new preventive benefits and payment system reforms that promote access, efficiency, and prudent use of taxpayer dollars. These reforms are critical to strengthening and protecting Medicare for the future. The Medicare Trust Fund, which was projected to

be insolvent by 1999 when President Clinton took office, is now projected to be solvent until 2015.

Coverage of new preventive health benefits is among the BBA's most significant impacts on patient care. We have:

- expanded coverage for test strips and education programs to help diabetics control their disease;
- begun covering bone density measurement for beneficiaries at risk of osteoporosis;
- begun covering several colorectal cancer screening tests;
- expanded preventive benefits for women so Medicare now covers a screening pap smear, pelvic exam and clinical breast exam every three years for most women, and every year for women at high risk for cervical or vaginal cancer; and,
- begun covering annual screening mammograms for women age 40 and over, and a one-time initial, or baseline, mammogram for women ages 35-39, paying for these tests whether or not beneficiaries have met their annual deductibles.

And, as of January 1, 2000, we will begin to cover prostate screening, as well. These important additions to the Medicare benefits package will have a substantial impact on patient care by helping to prevent problems and identify them at earlier, more treatable stages.

The BBA also made substantial changes to the way Medicare reimburses providers in the fee-for-service program. We have made solid progress in implementing these payment reforms. For example, we have:

- modified inpatient hospital payment rules;
- established a prospective per diem payment system for skilled nursing facilities to encourage facilities to provide care that is both efficient and appropriate;
- refined the physician payment system, as called for in the BBA, to more accurately reflect practice expenses for primary and specialty care physicians;
- initiated the development of prospective payment systems for home health agencies, outpatient hospital care, and rehabilitation hospitals that will be implemented once the Year 2000 computer challenge has been addressed; and,
- begun implementing an important test of whether market competition can help Medicare and its beneficiaries save money on durable medical equipment and supplies.

We have fully implemented the majority of the BBA's more than 300 provisions affecting our programs, including the Medicare+Choice program. While the statute generally prescribes in detail the changes we are required to make, we are committed to exercising the maximum flexibility within our limited discretion in our implementation of these provisions.

It is clear that the BBA is succeeding in promoting efficiency, slowing growth of Medicare expenditures, and extending the life of the Medicare Trust Fund. However, according to both the HCFA actuaries and the Congressional Budget Office, the BBA is only one factor contributing to changes in Medicare spending. Low inflation from a strong economy is having an impact on total spending. Slower claims processing during the transition to new payment systems is contributing to a temporary slow-down in overall spending. And we have made substantial strides in fighting fraud, waste and abuse that have significantly decreased the amount of improper payments. For the first time ever, the hospital case mix index declined last year due to efforts to stop "upcoding," or billing for more serious diagnoses than patients actually have in order to obtain higher reimbursement.

Change of this magnitude always requires adjustment. It is not surprising that some market corrections would result from such significant legislation. We are proactively monitoring the impact of the BBA to ensure that beneficiary access to covered services is not compromised. We are evaluating this information to assess the impact of BBA changes on beneficiaries and to determine what changes may need to be made to ensure continued access to quality care.

Thus far, our monitoring reveals evidence of isolated but significant problems. For example, there is reason to be concerned that some beneficiaries are not getting necessary care because of the BBA's \$1500 caps on certain outpatient rehabilitation therapies. We want to continue working with beneficiaries, providers, and Congress to closely monitor the situation, evaluate any evidence of problems in access to quality care, and develop appropriate, fiscally responsible solutions.

Because of our concerns, the President's Medicare reform plan sets aside \$7.5 billion from fiscal 2000 to fiscal 2009 to smooth out implementation of BBA payment reforms that may be adversely affecting beneficiary access to high quality care. Where there is credible evidence that adjustments are necessary to protect access to care, we want to work with the Congress to make appropriate adjustments. The President's reform plan also dedicates a portion of the budget surplus to Medicare. This will help prevent excessive cuts in provider payment that otherwise would be

necessary in the future as Medicare enrollment is expected to double over the next 30 years, and increased efficiencies alone will not be able to cover the increased costs.

The President's plan also includes administrative actions to assure a smooth implementation process, and we are continuing to explore other actions. Those already underway address several key areas of concern:

- *Inpatient hospital transfers.* The BBA requires the Secretary to reduce payments to hospitals when they transfer patients to another hospital or unit, skilled nursing facility or home health agency for care that is supposed to be included in acute care payment rates for ten diagnoses. It also authorizes HCFA to extend this "transfer policy" to additional diagnoses after October 1, 2000. To minimize the impact on hospitals, we are delaying extension of the transfer policy to additional diagnoses for two years.
- *Hospital outpatient payments.* The BBA requires Medicare to begin paying for hospital outpatient care under a prospective payment system, similar to what is used to pay for hospital inpatient care. To help all hospitals with the transition to outpatient prospective payment, we are considering delaying a "volume control mechanism" for the first few years of the new payment system. The law requires Medicare to develop such a mechanism because prospective payment includes incentives that can lead to unnecessary increases in the volume of covered services. The proposed prospective payment rule presented a variety of options for controlling volume and solicited comments on these options. Delaying their implementation would provide an adjustment period for providers as they become accustomed to the new system.

We also are considering implementing a three-year transition to this new PPS by making budget-neutral adjustments to increase payments to hospitals that would otherwise receive large payment reductions such as low-volume rural and urban hospitals, teaching hospitals, and cancer hospitals. Without these budget-neutral adjustments, these hospitals could experience large reductions in payment under the outpatient prospective payment system.

And, to help hospitals under the outpatient prospective payment system, we included a proposal in the proposed rule to use the same wage index for calculating rates that is used to calculate inpatient prospective payment rates. This index would take into account the effect of hospital reclassifications and redesignations. For all of these outpatient department reform options, the rule-making process precludes any definitive statement on administrative actions until after the implementing rule is published.

- *Rural hospital reclassification.* Hospital payments are based in part on average wages where the hospital is located. We are making it easier for rural hospitals whose payments now are based on lower, rural area average wages to be reclassified and receive payments based on higher average wages in nearby urban areas and thus get higher reimbursement. Right now, facilities can get such reclassifications if the wages they pay their employees are at least 108 percent of average wages in their rural area, and at least 84 percent of average wages in a nearby urban area. We are changing those average wage threshold percentages so more hospitals can be reclassified.
- *Home health.* The BBA significantly reformed payment and other rules for home health agencies. We are taking several new steps to help agencies adapt to these changes. We are increasing the time for repayment of overpayments related to the interim payment system from one year to three years, with one year interest free. Currently, home health agencies are provided with one year of interest free extended repayment schedules. We are postponing the requirement for surety bonds until October 1, 2000, when we will implement the new home health prospective payment system. This will help ensure that overpayments related to the interim payment system will not be an obstacle to agencies obtaining surety bonds.

We also are following the recommendation of the General Accounting Office by requiring all agencies to obtain bonds of only \$50,000, not 15 percent of annual agency Medicare revenues as was proposed earlier. We are eliminating the sequential billing rule as of July 1, 1999. Many home health agencies had expressed concern about the impact of the implementation of this requirement on their cash flows and this measure should alleviate these problems to a large degree. And we are phasing-in our instructions implementing the requirement that home health agencies report their services in 15-minute increments in response to concerns that the demands of Y2K compliance were competing with agency efforts to implement this BBA provisions. Allowing this degree of flexibility for a temporary period will prevent agency cash flow problems or returned claims.

It is important to note that the BBA is only one factor contributing to challenges providers face in the rapidly evolving health care market place. Efforts to pay correctly and promote efficiency may mean that Medicare no longer makes up for losses or inefficiencies elsewhere. We are concerned about reports on the financial conditions of some individual and chain providers.

It is essential that we try to delineate the BBA's impact from the effects of excess capacity, discounted rates to other payers, aggressive competition, imprudent business decisions, and other practices and market factors not caused by the BBA. And, as is underscored by the title of this hearing, it is essential that we focus on the impact on beneficiary access to high quality patient care.

Monitoring Access

These payment reforms have created change for many of our providers. As mentioned above, our first and foremost concern continues to be the effect of policy changes on beneficiaries' access to affordable, quality health care. We are proactively monitoring the impact of the BBA to ensure that beneficiary access to covered services is not compromised. We are systematically gathering data several sources to look for objective information and evidence of the impact of BBA changes on access to quality care, including:

- beneficiary advocacy groups;
- health plans and providers;
- Area Agencies on Aging;
- State Health Insurance Assistance Programs;
- claims processing contractors;
- State health officials; and
- media reports.

We also are examining information from the Securities and Exchange Commission and Wall Street analysts on leading publicly traded health care corporations. This can help us understand trends and Medicare's role in net income, revenues and expenses, as well as provide indicators of liquidity and leverage, occupancy rates, states-of-operation, lines of business exited or sold by the company, and other costs which may be related to discontinued operations.

We are examining Census Bureau data, which allow us to gauge the importance of Medicare in each health service industry, looking at financial trends in revenue sources by major service sectors, and tracking margin trends for tax-exempt providers.

We are monitoring the Bureau of Labor Statistics monthly employment statistics for employment trends in different parts of the health care industry. Such data show, for example, that the total number of hours worked by employees of independent home health agencies is at about the same level as in 1996. That provides a more useful indicator of actual home health care usage after the BBA than statistics on the number of agency closures and mergers. The data also show that nursing homes may be slightly reducing the number of employees and the hours that they work.

The HHS Inspector General's office has interviewed hospital discharge planners and nursing home administrators about the BBA's impact on patient care. They found that the proportion of beneficiaries discharged to skilled nursing facilities is unchanged from 1996. Hospital lengths of stay have not increased. Less than 1 percent of nursing home administrators say the prospective payment system is causing access to care problems. However, about one in five discharge planners say it takes more time to place Medicare patients in nursing homes, while only 1 percent say it is "very difficult" to make such placements.

The Inspector General's Office also found that both nursing home administrators and hospital discharge planners say nursing facilities are requesting more information before accepting patients. About half of the nursing home administrators say they are less likely to accept patients requiring expensive supplies or services such as ventilators or expensive medications, about half also say they are more likely to admit patients who require special rehabilitation services such as physical therapy following joint replacement surgery.

The Inspector General's office also has agreed to interview discharge planners about access to home health care following BBA payment reforms, and the impact of the \$1500 caps on outpatient therapy.

Specific BBA Provisions

Outpatient Rehabilitation Therapy: The BBA imposed \$1500 caps on the amount of outpatient rehabilitation therapy services that can be reimbursed, except in hospital outpatient clinics. However, these caps are not based on severity of illness or care needs, and they appear to be insufficient to cover necessary care for many

beneficiaries. Beneficiary groups are reporting many instances of problems with this cap, and we are very concerned about their adverse impact, particularly on individuals in nursing homes. As mentioned above, our HHS Inspector General colleagues have agreed to study this problem. We are providing data to the Medicare Payment Advisory Commission so it can analyze patterns of therapy service usage. And we will continue to work with Congress and others to determine what adjustments to the cap should be made.

Skilled Nursing Facilities: We implemented the new skilled nursing facility prospective payment system called for in the BBA on July 1, 1998. The old payment system was based on actual costs, subject to certain limits, and included no incentives to provide care efficiently. The new system uses average prices adjusted for each patient's clinical condition and care needs, as well as geographic variation in wages. It creates incentives to provide care more efficiently by relating payments to patient need, and enables Medicare to be a more prudent purchaser of these services.

The BBA mandated a per diem prospective payment system covering all routine, ancillary, and capital costs related to covered services provided to beneficiaries under Medicare Part A. The law requires use of 1996 costs as the base year, and implementation by July 1, 1998 with a three year transition blending facility-specific costs and prospective rates. It did not allow for exceptions to the transition, carving out of any service, or creation of an outlier policy. We are carefully reviewing the possibility of making administrative changes to the PPS.

We held a town hall meeting earlier this year to hear a broad range of skilled nursing facility concerns, and we continue to meet with provider and beneficiary representatives. There are concerns that the prospective payment system does not adequately reflect the costs of non-therapy ancillaries such as drugs for high acuity patients.

We are conducting research that will serve as the basis for refinements to the resource utilization groups that we expect to implement next year. We expect to have the research completed by the end of the year and to then develop refinements that we will be able to implement next October. Under the statute, we have the authority to refine these groups and redistribute money across categories in a budget neutral manner. We do not have discretion under the law to increase the overall level of payments to skilled nursing facilities. We fully expect that we will need to periodically evaluate the system to ensure that it appropriately reflects changes in both care practice and the Medicare population.

Home Health: The BBA closed loopholes that had invited fraud, waste and abuse. For example, it stopped the practice of billing for care delivered in low cost, rural areas from urban offices at high urban-area rates. It tightened eligibility rules so patients who only need blood drawn no longer qualify for the entire range of home health services. And it created an interim payment system to be used while we develop a prospective payment system. We expect to have the prospective payment system in place by the October 1, 2000 statutory deadline. We expect to publish a proposed regulation this fall so we can begin receiving and evaluating public comments, and publish a final rule in July 2000.

The interim payment system is a first step toward giving home health agencies incentives to provide care efficiently. Before the BBA, reimbursement was based on the costs they incurred in providing care, subject to a per visit limit, and this encouraged agencies to provide more visits and to increase costs up to the limits. The interim system includes a new, aggregate per beneficiary limit designed to provide incentives for efficiency that will be continued under the episode-based prospective payment system.

Last year Congress increased the cost limits in an effort to help agencies during the transition to prospective payment. We are also taking steps to help agencies adjust to these changes, and in March we held a town hall meeting to hear directly from home health providers about their concerns. We are increasing the time for repayment of overpayments related to the interim payment system to three years, with one year interest free. And, effective July 1, we ended the sequential billing policy that had raised cash flow concerns for some agencies. Sequential billing was designed to ensure proper allocation of home health expenditures between Part A and Part B that is required by changes to financing of the benefit included in the BBA. We have determined we can accomplish this allocation through other means.

At the same time, we are implementing the Outcome and Assessment Information Set (OASIS). OASIS fulfills a statutory mandate for a "standardized, reproducible" home care assessment instrument. It will help home health agencies determine what care patients need. It will help improve the quality of care. And it is essential for accurate payment under prospective payment.

To date, evaluations by us and the GAO have not found that reduced home health spending is causing significant quality or access problems. However, we have heard serious reports from beneficiary groups, our regional offices, and others regarding home health agencies that have inappropriately denied or curtailed care and incorrectly told beneficiaries that they are not eligible for continuing services. This may result from a misunderstanding of the new incentives to provide care efficiently, or from efforts to "cherry pick" low cost patients and game the system. The Congressional Budget Office attributes some of the lower health spending to the fact that agencies are incorrectly treating the new aggregate per beneficiary limit as though it applies to each individual patient.

Recognizing this, we have therefore provided home health agencies with guidance on the new incentives and their obligation to serve all beneficiaries equitably. We have instructed our claims processing contractors to work with agencies to further help them understand how the limits work. Because home health beneficiaries are among the most vulnerable, we are continuing ongoing detailed monitoring of beneficiary access and agency closures. And, as mentioned above, we have taken several administrative steps to help home health agencies adjust to BBA changes, such as extending the time for them to repay overpayments.

Hospitals: We have implemented the bulk of the inpatient hospital-related changes included in the BBA in updated regulations. We have implemented substantial refinements to hospital Graduate Medical Education payments and policy to encourage training of primary care physicians, promote training in ambulatory and managed care where beneficiaries are receiving more and more services, curtail increases in the number of residents, and slow the rate of increase in spending. We have implemented provisions designed to strengthen rural health care systems. We have carved out graduate medical education payments from payments to managed care plans and instead are paying them directly to teaching hospitals (and are proposing in the President's Medicare reform plan to similarly carve out disproportionate share hospital payments).

The BBA also called for a prospective payment system for outpatient care, which we expect to implement next year. The outpatient prospective payment system will include a gradual correction to the old payment system in which beneficiaries were paying their 20 percent copayment based on hospital charges, rather than on Medicare payment rates. Regrettably, implementation of the prospective payment system as originally scheduled would have required numerous complex systems changes that would have substantially jeopardized our Year 2000 efforts. We are working to implement this system as quickly as the Year 2000 challenge allows. We issued a Notice of Proposed Rule Making in September 1998 outlining plans for the new system so that hospitals and others can begin providing comments and suggestions. We are actively reviewing all of the comments from the industry and other interested parties that we received during the comment period, which we extended until July 30.

We are focusing most of our continuing work on rural, inner city, cancer, and teaching hospitals because our analysis suggests that the outpatient prospective payment system will have a disproportionate impact on these facilities. We are reviewing the many comments we have received on the proposed regulation and we are continuing to develop modifications to the system for inclusion in the final rule.

In addition to our work on the outpatient prospective payment system, we are proactively monitoring the impact of all Medicare payment changes on hospitals.

Physicians: As directed by the BBA, we are on track in implementing the resource-based system for practice expenses under the physician fee schedule, with a transition to full implementation by 2002 in a budget-neutral fashion that will raise payment for some physicians and lower it for others. The methodology we used addresses many concerns raised by physicians and meets the BBA requirements. We fully expect to update and refine the practice expense relative value units in our annual regulations revising the Medicare fee schedule. We included the BBA-mandated resource-based system for malpractice relative value units in this year's proposed rule. We welcome and encourage the ongoing contributions of the medical community to this process, and we will continue to monitor beneficiary access to care and utilization of services as the new system is fully implemented.

The President's fiscal 2000 budget contains a legislative proposal for a budget-neutral technical fix to ensure the BBA's sustainable growth rate (SGR) for physician payment. Medicare payments for physician services are annually updated for inflation and adjusted by comparing actual physician spending to a national target for physician spending. The BBA replaced the former physician spending target rate of growth, the Medicare Volume Performance Standard, with the SGR. The SGR takes into account price changes, fee-for-service enrollment changes, real gross domestic product per capita, and changes in law or regulation affecting the baseline.

After BBA was enacted, HCFA actuaries discovered that the SGR system would result in unreasonable year-to-year fluctuations. Also, the SGR target cannot be revised to account for new data.

CONCLUSION

The BBA made important changes to the fee-for-service Medicare program to strengthen and protect it for the future. These changes, along with a strong economy and our increased efforts to combat fraud, waste, and abuse, have extended the life of the Trust Fund until 2015. With changes of the magnitude encompassed in the BBA, some issues have arisen that may require adjustment and fine tuning. The President's Medicare reform plan sets aside \$7.5 billion to smooth out implementation of BBA reforms. It dedicates a portion of the budget surplus to Medicare, which will help protect against excessive provider payment reductions in the future as Medicare enrollment doubles over the next 30 years, and increased efficiencies alone will not be able to cover the increased costs. The President's plan also includes administrative adjustments to help in the transition to new payment systems.

It is not surprising that necessary market corrections would result from such significant legislation. As always, we remain concerned about the effect of policy changes on beneficiaries' access to affordable, quality health care. We are proactively monitoring the impact of the BBA to ensure that beneficiary access to covered services is not compromised. We welcome the opportunity to look at any new information regarding beneficiary access to quality care. We are committed to continuing to look at refinements to the BBA that are within our administrative authority. We look forward to continuing to work with this Committee to identify concerns, and we will keep you up to date on the status of implementation of the BBA.

The President is committed to working with Congress to enact bipartisan Medicare reform this year that includes more competition in the program, a long overdue prescription drug benefit that is available and affordable for all beneficiaries, and that dedicates a significant portion of the budget surplus to Medicare, and sets aside funding specifically for smoothing out the transition to BBA payment reforms.

I thank you for holding this hearing, and I am happy to answer your questions.

Mr. BILIRAKIS. Thank you, Michael. Thank you, Mr. Administrator. And I also want to thank you for having members of your staff stay after your testimony. I know you have to go. In fact, we have run later than we expected in the opening statements and I appreciate your patience in that regard.

And we will get together. I appreciate your offer. I know it was not necessary because we have sat around a table in the past and tried to work things out and hopefully we can do that on a bipartisan basis. I have already talked to Mr. Brown and hopefully we can do that sooner rather than later.

You say that you are committed to exercising the maximum flexibility—I am putting words in your mouth, I suppose—within your limited discretion to implement the provisions of BBA 1997. There has been, of course, a lot of controversy around what you, HCFA, can do administratively and what would require a legislative fix. I have always felt that handling things administratively, without going into legislative fixes, is certainly the best way to go.

Hopefully, after taking notes here on some of these comments and the questioning that takes place, your personnel will get together with you and hopefully you can furnish in writing, possibly at the gathering that we will have, an idea of some of the things that you can do through administrative fixes.

And I appreciate the fact that there has to be an admission—maybe that is the wrong word—that a fix is necessary. In other words, there is something wrong, whether it is the BBA specifically or whether it was the interpretation of BBA. We have talked about that in the past and certainly there has to be an acknowledgement that fixes are necessary because there is a wrong there somewhere.

So I would appreciate it if you would listen to all of these things through your staff and address them and we can get these things worked out.

Mr. HASH. Mr. Chairman, in relation to the request from Chairman Bliley, we will certainly furnish the committee our view of those areas that are within the discretion of the executive branch to have flexibility, and those areas in which we believe statutory provisions are at the root of the issue and need to be addressed.

Mr. BILIRAKIS. Yes. I guess we are talking here now—would it be better if we waited until we got together with everybody to find out? Some of the areas of concern we will not have an opportunity to address in a formal hearing like this. So would you suggest you might do that prior to that gathering? What do you think?

Mr. HASH. I believe we would be prepared to furnish—as you know, Mr. Chairman, this is, as you pointed out, not a new subject and we have been spending a lot of time, both within our own policy deliberations and also in consultation with the department's legal counsel, to investigate thoroughly those areas of the statute where discretion was given.

I do not have to tell you, the BBA was, I think in most people's judgment, extraordinarily specific and prescriptive in its statutory provisions. In many areas, I believe that we do not have any discretion on the executive side to modify what is very clear and direct and explicit in the statute.

And because we have spent a lot of time parsing that question, we are prepared to—in fact, many of the things I just went through in my opening statement reflecting steps we have taken in the hospital area, in the SNF area, in the home health area, are, in fact, a reflection of the judgments we have made about the flexibility that we have.

Mr. BILIRAKIS. Well, I tend to agree. For instance, you have interpreted the outpatient statutory language in such a way that hospital outpatient payments are \$900 million less per year or \$4.5 billion over 5 years. This is due, I think you would agree, to your interpretation of the beneficiary coinsurance issue. And yet 253 members of the House, including 23 members of this committee and 77 members of the Senate, have said through communications with you that this is not what Congress intended.

So I do not know that I am asking you to respond to that at this point in time or whether we might be able to work this out later on.

Mr. HASH. This is one of the issues, Mr. Chairman, which we have under active review now. We have been looking carefully and thoroughly at both the legislative history and the statutory provisions with respect to the outpatient hospital prospective payment system and we have asked the general counsel at HHS to give us advice about the extent to which we do have flexibility with regard to the interpretation of how we calculate those prospective rates, the conversion factor and so forth in the setting of the outpatient coinsurance amounts.

We want to be responsive where we can. We have not come to a complete conclusion of that review, so that is an issue that we are actively reviewing right now.

Mr. BILIRAKIS. Then I am going to yield to Mr. Brown in a moment. I just would want to alert you to the interim practice expense values—regarding cardiac surgery, etc.—which were done a while back and apparently HCFA is now issuing a new rule that is printed in the Federal Register. Not going into the merits of that or anything at this point in time but I would just really alert you to the fact that we probably would discuss that.

I now yield to Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. Hash, thank you again for joining us and for your always cooperative attitude in your work with us. I know it has not been an easy time for you as Congress and every provider in the country points the finger at you and you and HCFA overall. You have been an easy target, I guess, because you are the most logical and most obvious target.

I think, first of all, that all of us bear some responsibility for this situation clearly. This Congress does. This committee does. HCFA does. And we also bear responsibility because Congress imposed some 300 modifications on HCFA and I applaud your work and my understanding already is that you have implemented more than half of those 300 provisions from the Balanced Budget Act. So for that, you should be congratulated and people should know that.

I know that HCFA is looking at data from a wide variety of sources to monitor the effects of BBA implementation on beneficiaries and on providers. Elaborate if you would on some of those monitoring efforts and your findings to date, especially those that relate to seniors' access to care. How are you monitoring those changes? What have you found?

Mr. HASH. Mr. Brown, as I said a moment ago, none of us is happy with the extent of information that is available on a timely basis to do the kind of comprehensive assessment that is called for here, but within those kinds of constraints, what we have been doing falls into several categories.

One, we have been reviewing data that is provided routinely by the Bureau of Labor Statistics in the Department of Labor to assess changes in participation in the workforce of health care providers. They break out employment by health care provider type—hospitals, home health agencies and skilled nursing facilities—and we have been looking at those figures.

For example, in the case of home health agencies, we have seen a decline in the participation in the workforce, but obviously from what we know about the mergers and voluntary withdrawals of home health agencies, one would expect that to be the case.

In the case of employment in the hospital sector, it continues to increase on a monthly basis. It is not growing at the same rate that it had been growing, but there are clearly indications that the labor force in the hospital industry is continuing to grow.

We also are reviewing as much information as we can get from other surveys and data sources, including AMA surveys and AHA panel surveys. There are a number of Wall Street analysts who examine sectors of the health care system that are publicly traded companies. And we have been doing monitoring through our regional offices, working with advocacy groups and with States and others to try to get a clearer picture of the impacts.

I think as the GAO and the IG, with whom we have also been relying to help us with this monitoring, have tentatively summarized to this point is that we have not seen any systematic evidence that quality or access to Medicare-covered services has been compromised.

Now that is not to say that there are not anecdotes and instances that people have brought to our attention that suggest that we need to make some changes, some midcourse corrections, but so far, we have not actually been able to determine that there is a body of evidence out there that suggests that across the board there are certain fixes that ought to be made.

Again though, we continue to update this information and we are anxious, through whatever sources, and as you know, we have actually solicited pretty aggressively the provider organizations to help us collect and get information about BBA impacts and we are continuing to review that and are trying to put that into the mix for the kinds of proposals that we would like to suggest to implement the President's commitment to make some changes to the BBA for the remaining years covered by the act.

Mr. BROWN. Thank you.

Let me shift gears for a moment. Several of us on this committee have worked on H.R. 1579, the Children's Hospital Education and Research Act. Mr. Dingell is a cosponsor. Mr. Bilirakis is a cosponsor.

The Medicare Commission, if you remember, the instructions for it include a request to commissioners to look at GME for free-standing children's hospitals. Ms. DeGette has been involved in that and several others on this committee. I believe almost every member of the commission recommended doing something. The President has put some money, not as much as our legislation asks for but some money in his budget.

As you know, they get very little Federal graduate medical education money because only end stage renal disease expenditures, the Medicare expenditures, go to those hospitals.

Would you support some sort of children's hospital GME grant program?

Mr. HASH. Yes, Mr. Brown, we would and have. Actually as a part of the President's proposal, it is a grant proposal that would be administered by another part of HHS, the Health Resources and Services Administration.

We recognize that the formula Medicare uses to determine graduate medical education payments does not work in the children's hospital setting. And to ensure that children's hospitals that are engaged in graduate medical education for the next generation of pediatricians and subspecialties in children's care, we want to make sure that those graduate medical education programs are financed adequately and fairly and we would like to work with you to push that issue forward. The President and the administration strongly support a grant program to assist in the cost of graduate medical education for children's hospitals.

Mr. BILIRAKIS. And I would lend my little bit of weight to that effort. Certainly I endorse it and we should work together on that.

Let's see. Dr. Ganske?

Mr. GANSKE. Thank you. Thank you, Mr. Chairman. And thank you, Mr. Hash, for being here.

In my opening statement I talked a little bit about hospitals and we have talked about unintended consequences but I want to focus a little bit on another provider group and specifically how well HCFA is following the law in terms of the BBA.

You know, we have general practitioners, family practitioners and surgeons out in rural areas that because there is a very high percentage of elderly in those areas, really depend on Medicare to be fair.

Now in the Balanced Budget Act we established a sustainable growth rate system or SGR to control spending growth under Medicare's physician fee-for-service schedule. For the 1998 SGR, HCFA estimated that the gross domestic product would only grow at 1.1 percent, a projection that turned out to be one-third of actual GDP growth.

Then HCFA made an even more serious error in the 1999 SGR when it estimated that Medicare Plus Choice enrollment would grow by 29 percent. We know that that hasn't happened.

Those estimates have already cost the physician payment system \$3 billion. Yet to my knowledge, HCFA has done nothing to correct those errors. If they remain uncorrected, I am afraid we are going to see the physicians in those rural areas move into the cities and I think that they could lead to severe payment cuts to physicians in future years.

Do you have any plans to address that problem? Do you have any plans to restore the money the physicians have lost to HCFA already?

Mr. HASH. Dr. Ganske, I am glad you brought that up because we do have plans and we do, in fact, have a proposal that is pending before the Congress now to deal with two aspects of the sustainable growth rate procedure for physician service payments.

The two changes that we are proposing in the statute are that the volatility of the factors that are used to calculate that limit be changed in a way that makes it more predictable. It is a more complicated way of making these changes than I can articulate here, but a lot of analysts who know more about this than I do have looked at the sustainable growth limit methodology and have found it to produce wide swings in terms of the estimates that come out of it or the targets that come out of it, I should say. And we have a proposal to fix that.

Second, on the estimation errors, two of which you have just pointed to, we have a proposal that allows us to correct the sustainable growth rate limit for future years to reflect estimation errors.

Under the current language in the BBA, we do not believe we have the authority to correct estimation errors and we would very much like to do that. We think that would be the fair and appropriate thing to do with respect to physician payments.

Mr. GANSKE. Let me just follow this up. The AMA and other specialty groups wrote the HCFA administrator about their concerns with projection errors in the sustainable growth rate on December 2, 1998 within the comment period of HCFA's November 2, 1998 SGR notice. Then they sent another letter to HCFA about this problem on May 21, 1999.

Has HCFA ever responded to those letters from the physician community or at least let doctors know that the administration is concerned about this? Do you have any copies of replies to those letters?

Mr. HASH. I do not have them with me, but I will be happy to furnish them. I am not aware of their status, but they should have been answered and, if not, they will be answered promptly, but I would expect they have been answered and I would be happy to furnish copies of the letters to you.

[The following was received for the record:]

Generally, we do not respond, in correspondence format, to letters submitted as comments on a proposed notice published in the *Federal Register*. We address comments in the final notice when it is published in the *Federal Register*. The comments you refer to were responded to in our final notice that was published on Friday, October 1, 1999. Attached is a copy of the notice for inclusion as part of the transcript (See page 53396, column 1, under Roman Numeral IV, *Comment*:). In addition, the May 21, 1999, letter you asked about was responded to on September 24, 1999. Copies of their May 21 letter and our September 24 response also are attached for inclusion as part of the transcript.

and Drug Administration, 7500 Sandish Pl., Rockville, MD 20855, 301-827-6956.

SUPPLEMENTARY INFORMATION:

I. Background

Section 116 of the Food and Drug Administration Modernization Act (the Modernization Act) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a). This section provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such change. Elsewhere in this issue of the *Federal Register*, FDA is proposing to amend its regulations on supplements and other changes to an approved application § 514.8 (21 CFR 514.8) to conform to section 506A of the act.

The purpose of this draft guidance is to provide recommendations to holders of NADA's and ANADA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 514.8. The draft guidance covers recommended reporting categories for postapproval changes for new animal drugs. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) size, (3) manufacturing process, (4) specification(s), (5) package, and (6) miscellaneous changes. This draft guidance does not provide recommendations on the specific information that should be developed by an applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product. FDA has published guidances, including the Scale-up and Postapproval Changes (SUPAC) guidances, that provide recommendations on reporting categories and/or the type of information that should be developed by the applicant to validate the effect of the change on the identity, strength, quality, purity, or potency of a product as they may relate to the safety or effectiveness of the product. The draft guidance, which cites proposed § 514.8, will be revised based on public comments and implemented for use as a companion document when § 514.8 is finalized.

This draft guidance represents the agency's current thinking on this subject. It does not create or confer any

rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

II. Comment

Interested persons may, on or before December 15, 1999, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at "http://www.fda.gov/cvm".

Dated: June 23, 1999.
Margaret M. Beaud,
Acting Associate Commissioner for Policy.
[FR Doc. 99-25492 Filed 9-30-99; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration (HCFA-3025-J)

Medicare Program; Notice of the Implementation of the Medicare Lifestyle Modification Program Demonstration Project

AGENCY: Health Care Financing Administration (HCFA), HHS.
ACTION: Notice.

SUMMARY: This notice announces our implementation of the Medicare Lifestyle Modification Program Demonstration. Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. Such programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion.

FOR FURTHER INFORMATION CONTACT: Arnon Thousmaian, Ph.D. at (410) 786-6672, or Athousmaian@HCFA.GOV.

SUPPLEMENTARY INFORMATION: The purpose of this demonstration is to test the feasibility and effectiveness of

providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. This demonstration will test a proven and intensive program designed to reduce or reverse the progression of cardiovascular disease (CAD) of patients at risk for invasive treatment procedures. The demonstration will be conducted over a 4-year period at an estimated 15 sites. Enrollment is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy clinical admission criteria.

We are preparing to expand this demonstration to at least one additional nationwide, multi-site cardiovascular lifestyle modification program. An announcement of this expanded demonstration to solicit interested programs is expected within the next several weeks.

We will conduct an independent evaluation of both demonstrations to compare the short-term and long-term outcomes and costs in providing this type of service for Medicare beneficiaries.

Authority: 42 U.S.C. 1395b-1(a)(1)(K) and (a)(2).

Catalog of Federal Domestic Assistance: Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: September 14, 1999.

Michael M. Bush,
Deputy Administrator, Health Care Financing Administration.
[FR Doc. 99-25416 Filed 9-28-99; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration (HCFA-1008-FM)

RN 6038-AJ00

Medicare Program; Sustainable Growth Rate for Fiscal Year 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the fiscal year 2000 Sustainable Growth Rate (SGR) for expenditures for physicians' services under the Medicare Supplementary Medical Insurance (Part B) program as required by section 1848(b) of the Social Security Act (the Act). The SGR for fiscal year 2000 is 2.1 percent.

EFFECTIVE DATE: The provisions of the Medicare SGR for fiscal year 2000 contained in this notice are effective on October 1, 1999.

FOR FURTHER INFORMATION CONTACT:
Raymond Bulle, (410) 786-7287.
SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Sustainable Growth Rate

Section 1848(f) of the Social Security Act (the Act), as amended by section 4503 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33), enacted on August 5, 1997, replaces the volume performance standard with a Sustainable Growth Rate (SGR) standard. It specifies the formula for establishing yearly SGR targets for physicians' services under Medicare. The use of SGR targets is intended to control the actual growth in Medicare expenditures for physicians' services.

The SGR targets are not limits on expenditures. Payments for services are not withheld if the SGR target is exceeded. Rather, the appropriate fee schedule update, as specified in section 1848(d)(3)(A) of the Act, is adjusted to reflect the success or failure in meeting the SGR target.

Amended section 1848(f)(2) of the Act states that "the sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998) shall be equal to the product of—

(A) 1 plus the Secretary's estimate of the weighted-average percentage increase (divided by 100) in the fees for all physicians' services in the fiscal year involved;

(B) 1 plus the Secretary's estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous fiscal year to the fiscal year involved;

(C) 1 plus the Secretary's estimate of the projected percentage growth in real gross domestic product per capita (divided by 100) from the previous fiscal year to the year involved; and

(D) 1 plus the Secretary's estimate of the percentage change (divided by 100) in expenditures for all physicians' services in the fiscal year (compared with the previous fiscal year) which will

result from changes in law or regulations, determined without taking into account estimated changes in expenditures resulting from the update adjustment factor determined under subsection (d)(3)(B), minus 1 and multiplied by 100."

B. Physicians' Services

Because the scope of physicians' services covered by the SGR is the same as the scope of services that was covered by the Medicare volume performance standards, we are using the same definition of physicians' services for the SGR in this notice as we did for the Medicare volume performance standards published in the Federal Register (61 FR 59717) on November 22, 1996. That final notice announced the fiscal year 1997 volume performance standard rates and contained a detailed description of the scope of physicians' services.

II. Provisions of This Notice

Under the requirements in sections 1848(f)(2)(A) through (D) of the Act, as amended by section 4503 of the BBA, we have determined that the SGR for physicians' services for fiscal year 2000 is 2.1 percent. Our determination is based on the following statutory factors:

Statutory factors	Percent change
Fees	2.1
Enrollment	-1.8
Increase in Gross Domestic Product	1.8
Legislation	-0.2
Total	2.1

The specific calculations to determine the 2.1 percent SGR for physicians' services for fiscal year 2000 are explained below.

III. Calculation of the Fiscal Year 2000 Sustainable Growth Rate

Our explanation of how we determined the values for each of the four factors used in determining the SGR for fiscal year 2000 is as follows:

Factor 1—Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for Fiscal Year 2000

This factor was calculated as a weighted average of the calendar year 1998 and 2000 fee increases that apply during fiscal year 2000.

Most of the fees for physicians' services (as defined in section I. B. of this final notice) are updated by the Medicare Economic Index (MEI). However, the BBA provided for a 0.0 percent update in 1999 and 2000 for laboratory services, which represents about 11 percent of the Medicare-allowed charges for physicians' services. The following table, therefore, shows both the MEI and laboratory service updates that were used in determining the percentage increase in physicians' fees for fiscal year 2000.

MEDICARE ECONOMIC INDEX AND LABORATORY SERVICE UPDATE FOR CALENDAR YEARS 1999 AND 2000

	1999	2000
Medicare Economic Index	2.3	2.3
Laboratory Service	0.0	0.0

After taking into account all the elements described above, we estimate that the weighted-average increase in fees for physicians' services in fiscal year 2000, before applying any legislative adjustments to the MEI, will be 2.1 percent for all physicians' services.

Factor 2—The Percentage Change in the Average Number of Part B Enrollees From Fiscal Year 1999 to Fiscal Year 2000

Due to the growth in Medicare+Choice plan enrollees (whose Medicare-covered medical care is outside the scope of the SGR), we estimate that the average number of Medicare Part B enrollees, excluding those in Medicare+Choice plans, will decline by 1.8 percent. This decline was derived as follows:

Fiscal year	Average Medicare Part B enrollment (in millions)		
	Overall	Medicare+Choice	Overall, excluding Medicare+Choice
1999	36.886	6.116	30.750
2000	37.178	6.917	30.261
Percent change			-1.6

Factor 3—Estimated Real Gross Domestic Product Per Capita Growth in Fiscal Year 2000

Section 1848(f)(2)(C) of the Act, as amended by section 4503 of the BBA, requires the Secretary to project real gross domestic product per capita growth for the coming fiscal year. In calculating the SGR, we estimate that this growth will be 1.8 percent in fiscal year 2000.

Factor 4—Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Law or Regulations in Fiscal Year 2000 Compared With Fiscal Year 1999

Legislative changes contained in the BBA will have some residual effects on expenditures for physicians' services in fiscal year 2000. In addition, there are some miscellaneous provisions that will have a small impact.

Taking into account all of the changes in law or regulation that may affect expenditures for physicians' services, the decrease in expenditures for physicians' services is estimated to be -0.2 percent.

IV. The Use of Estimates in Computing the Sustainable Growth Rate

Section 1848(f) of the Act clearly requires that each year, the Secretary establish the SGR for the upcoming fiscal year beginning October 1 based on the Secretary's estimate(s) of four factors: The percentage increase in physicians' fees, the percentage increase in fee-for-service enrollment, the projected percentage growth in per capita gross domestic product, and the percentage change in expenditures for physicians' services resulting from changes in law or regulations. Because the calculation of the SGR for a given year is based on projected values, updates may be either lower or higher than they would have been if we had used later data. Thus, we initially considered revising estimates of the factors used in setting the SGR when later data had become available. However, as we indicated in the notice with comment period published in the *Federal Register* (63 FR 59188) on November 2, 1998, we had concerns about whether we had the statutory authority to make these revisions under current law and invited comments regarding how an adjustment could be made consistent with the law. The comments we received and our response are discussed below.

Comment: The American Medical Association and numerous physician organizations suggested that congressional intent should be

interpreted to authorize adjustments for projection error. These commenters also suggested a number of different approaches for making such adjustments. The various approaches suggested rely on later data.

Response: We do not believe that we have the authority to make adjustments based on Congressional intent because the statutory language clearly requires that estimated values be used for computing the SGR and there is no provision for revising the estimates to reflect later data. Our actions are controlled by the clear statutory language. Thus, we will not be able to make adjustments to the SGR based on later data.

However, the Administration's legislative package for fiscal year 2000, released in February 1999, contains a legislative proposal to adjust the SGR if later data are different from earlier estimates, as well as to address issues relating to the instability of the SGR discussed below. The changes proposed are all budget neutral. If Congress enacts this proposal for fiscal year 2000, we would revise the SGR for fiscal year 2000 as appropriate.

V. Technical Problems With the Sustainable Growth Rate System

We have begun to forecast the SGR for future years, and it appears that there is some instability in the SGR system. In the long-term, updates could oscillate between the maximum increase and decrease adjustments due to the use of mismatched time periods and the lag between measurement periods. The solution would be technical and would involve the matching of time periods for the SGR calculation, the actual versus target measurement, and the update adjustment. As discussed above the Administration has submitted a legislative proposal to the Congress that will address these factors and result in less oscillation in the physician fee schedule update.

VI. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we treat all physicians and suppliers as small entities. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural

hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Legislative changes contained in the BBA will affect expenditures for physicians' services in fiscal year 2000, although the impact will be slight, and residual effects will result in fiscal year 2000 from the calendar year implementation of these changes.

We are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

We have reviewed this final notice under the threshold criteria of Executive Order 13132 of August 4, 1999, and have determined that it does not significantly affect the rights, roles, and responsibilities of States.

(Sections 1848(d) and (f) of the Social Security Act) (42 U.S.C. 1395w-4(d) and (f)) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 1, 1999.

Michael M. Hash,
Deputy Administrator, Health Care Financing Administration

Approved: September 20, 1999.

Donna E. Shalela,

Secretary.

[FR Doc. 99-25527 Filed 9-28-99; 9:58 am]

BILLING CODE 4220-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3508(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed

May 21, 1999

DHHS/DCCM

1999 MAY 21 AM 11: 28

Ms. Nancy-Ann DeParle
Administrator
Health Care Financing Administration
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. DeParle:

The undersigned national medical organizations are writing to urge that the Health Care Financing Administration (HCFA) correct the estimates used to calculate the sustainable growth rate (SGR) for fiscal years 1998 and 1999 in accordance with actual data. In addition, we urge HCFA to make a proportionate adjustment to the 1999 conversion factor resulting from corrections to the SGR.

As required by the Balanced Budget Act of 1997 (BBA), the conversion factor update each calendar year involves establishing an update adjustment factor (UAF) that is adjusted annually by the SGR system. Establishment of the UAF and SGR involves estimates and projections of four factors: the percentage increase in fees for physician services, the percentage change in enrollment in the Medicare fee-for-service program, growth in gross domestic product (GDP), and the percentage change in expenditures for physician services due to law and regulations.

In regulations establishing the SGR for fiscal years 1998 and 1999, HCFA specifically discussed that its estimates of changes in GDP and Medicare fee-for-service enrollment were likely to prove erroneous once actual data on these factors became available. In 1998 and 1999, HCFA based the SGR on estimated GDP growth of 1.1 percent and 1.3 percent, respectively. Actual GDP growth for 1998 was almost 3 percent, and, based on available data for 1999, it appears that GDP growth could be even higher than in 1998. Further, HCFA estimated that Medicare fee-for-service enrollment for 1999 would decrease by 4.3 percent, although the Congressional Budget Office (CBO) has a much different estimate. Initially CBO projected that such enrollment would decrease by only 1.9 percent, but CBO more recently stated that changes in enrollment are likely to be even less than it had originally anticipated. Left uncorrected, errors in the HCFA estimates of the 1998 SGR alone would lead to a \$645 million shortfall in Medicare payments for physician services in 1999 and each year thereafter.

This is unacceptable, particularly since the SGR is cumulative, so errors in the SGR are not limited in their impact to only one year. Rather, they are compounded each year with each physician payment update. We do not believe Congress intended for physician payments to be based on erroneous calculations that could lead to potentially severe and unjustified payment decreases. HCFA should, therefore, immediately, or as soon as practicable in the case of 1999 projections—

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Nancy-Ann DeParle, HCFA Administrator

May 21, 1999

- Adjust its SGR estimate for fiscal year 1998 to reflect actual data on real per capita GDP growth and Medicare enrollment changes, as well as estimates of allowed expenditures for physician services impacted by these erroneous SGR calculations;
- Correct the 1999 conversion factor to reflect the corrected SGR; since the correct 1999 conversion factor should have been implemented on January 1, 1999, HCFA should "prorate" the conversion factor correction so that total payments for physician services this year will equal the total amount of payments that would have been made over the course of the year had the conversion factor been implemented correctly on January 1; and
- Revise the 1999 SGR, as well as estimates of allowed expenditures for physician services, to reflect available data on GDP growth and enrollment changes prior to computing the UAF to be used in establishing the 2000 payment update.

While HCFA had initially promised to adjust the 1998 and 1999 SGR to reflect actual data, it later expressed concern that it does not have the statutory authority to do so under existing law. We believe HCFA does have such authority to correct these errors, and that it is imperative for HCFA to accomplish this immediately.

HCFA must by regulation establish the SGR, along with estimates of each factor comprising the SGR, as set forth in section 1848(f)(2)(A) through (D) of the Social Security Act, 42 U.S.C. § 1395w-4(f)(2)(A) through (D), including estimates of changes in GDP and Medicare fee-for-service enrollment. Thus, the gap between HCFA's published estimates of and actual changes in enrollment and GDP growth is a result of regulatory action. Under section 1848(f)(2)(D), 42 U.S.C. § 1395w-4(f)(2)(D), Congress directed HCFA, in calculating the SGR, to estimate "the percentage change . . . in expenditures for all physicians' services in the fiscal year . . . which will result from changes in law and regulations. . . ." In accordance with this section, HCFA is authorized, and indeed required, by Congress to make adjustments to the SGR resulting from HCFA's erroneous projections that were part of a regulatory change.

Although we believe the BBA clearly provides HCFA with the statutory authority to correct any projection errors related to the SGR, to the extent that HCFA may assert otherwise, the legislative history to the BBA provides additional substantiation of Congress' intent that HCFA is to correct these projection errors.

The Balanced Budget Act of 1995 (the Act)—passed by Congress but vetoed by the President for reasons completely unrelated to the SGR—contained a provision mandating use of an SGR system to update payments for physicians services. During consideration of this legislation, the Physician Payment Review Commission (PPRC), an advisory body to Congress (and the predecessor to the Medicare Payment Advisory Commission (MedPAC)), made certain recommendations to Congress concerning an SGR type of system. Specifically, the PPRC suggested that a cumulative growth rate, such as the

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Nancy-Ann DeParle, HCFA Administrator

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SGR, replace the annual performance standard in effect under law existing at that time. In the PPRC's 1995 Report to Congress, in discussing "implementation of the cumulative approach," it stated that "[t]he delay before updates are determined could be shortened by using less complete information or projections for total actual spending. Additional spending not reflected in the estimates of spending in one year could be captured in the next ..."

The PPRC continued to have concern about this matter, which it addressed in its 1996 Report to Congress. It stated that "[o]ver time, more Medicare beneficiaries are expected to enroll in risk contract arrangements. This will make it harder to project fee-for-service Part B enrollment growth. The resulting errors in projection could become substantial, significantly affecting the accuracy of the conversion factor updates." To address these problems, the PPRC stated:

"Any revision to the Volume Performance Standard system should annually correct for any projection errors in the target growth rate from prior years. ... This limitation [projection errors] could be readily addressed by incorporating an adjustment into the sustainable growth rate that corrects for previous errors in the projection."

Since the PPRC was directed by Congress to review matters such as a cumulative growth rate system of reimbursement for physicians, and the PPRC submitted its recommendations to Congress under formal reports, Congress likely took the PPRC concerns stated above into consideration when enacting the SGR provisions under both budget acts. Thus, there is no reason for HCFA to assert that Congress did not anticipate SGR projection errors, which historically have been an issue of concern to policymakers and advisory bodies to Congress.

Accordingly, we urge HCFA to immediately adopt our above recommendations to correct its SGR projection errors for 1998, with a corresponding mid-year increase in the 1999 payment update for physicians' services.

Sincerely,

American Academy of Dermatology
 American Academy of Facial Plastic and Reconstructive Surgery
 American Academy of Family Physicians
 American Academy of Neurology
 American Academy of Ophthalmology
 American Academy of Otolaryngology Head and Neck Surgery
 American Academy of Physical Medicine and Rehabilitation
 American Association for Thoracic Surgery
 American Association of Clinical Endocrinologists
 American Association of Neurological Surgeons

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Nancy-Ann DeParle, HCFA Administrator

May 21, 1999

American College of Cardiology
 American College of Chest Physicians
 American College of Emergency Physicians
 American College of Gastroenterology
 American College of Obstetricians and Gynecologists
 American College of Osteopathic Surgeons
 American College of Physicians-American Society of Internal Medicine
 American College of Rheumatology
 American College of Surgeons
 American Gastroenterological Association
 American Geriatrics Society
 American Medical Association
 American Medical Group Association
 American Osteopathic Association
 American Psychiatric Association
 American Society for Gastrointestinal Endoscopy
 American Society for Therapeutic Radiology and Oncology
 American Society of Anesthesiologists
 American Society of Cataract and Refractive Surgery
 American Society of Clinical Oncology
 American Society of Clinical Pathologists
 American Society of General Surgeons
 American Thoracic Society
 American Urological Association
 Association of American Medical Colleges
 College of American Pathologists
 Congress of Neurological Surgeons
 Joint Council of Allergy, Asthma and Immunology
 Medical Group Management Association
 Renal Physicians Association
 Society of Cardiovascular and Interventional Radiology
 Society of Nuclear Medicine
 Society of Thoracic Surgeons



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

SEP 24 1999

Deputy Administrator
Washington, D.C. 20201

Mr. Jack Emery
Assistant Director, Department of Federal Affairs
American Medical Association
1101 Vermont Avenue, N.W.
Washington, D.C. 20005

Dear Mr. Emery:

Thank you for your letter to the Administrator regarding your recommendation that the Health Care Financing Administration (HCFA) revise the Sustainable Growth Rate (SGR) for fiscal year 1998, with a corresponding mid-year increase in the calendar year (CY) 1999 payment update for physicians' services. I am responding on her behalf, and I regret the delay in this response.

The Balanced Budget Act of 1997 requires the Secretary to publish, by August 1 of each year, an SGR based on estimates of the percentage increase in physician fees, the percentage increase in fee-for-service enrollment, the projected percentage growth in per capita gross domestic product, and the percentage change in physician expenditures resulting from changes in law or regulations. We initially considered revising estimates of the factors used in setting the SGR once actual data had become available for calculating the physician fee schedule update. However, we do not believe that we have the authority to make adjustments because the statutory language clearly requires that estimated values be used for computing the SGR and there is no provision for revising the estimates to reflect later data. Our actions are controlled by the clear statutory language, notwithstanding statements, such as those of the Physician Payment Review Commission that you cite, that may be argued to be indicative of Congressional intent. Thus, we will not be able to make adjustments to the SGR based on later data.

However, the Administration's legislative package for fiscal year 2000, released in February 1999, contains a legislative proposal to adjust the SGR if later data are different from earlier estimates, as well as to address issues relating to the instability of the SGR discussed below. The changes proposed are all budget neutral. If Congress enacts this proposal for fiscal year 2000, we would revise the SGR for fiscal year 2000 as appropriate. We have begun to forecast the SGR for future years, and it appears that the SGR system displays some instability. In the long term, updates could oscillate between the maximum increase and decrease adjustments due to the use of mismatched time periods and the lag between measurement periods. The solution would be technical and would involve the matching of time periods for the SGR calculation, the actual versus target measurement, and the update adjustment. The Administration's legislative proposal will address these factors and result in less oscillation in the physician fee schedule update.

A similar letter has been sent to the co-signers of your letter. I hope this information is helpful.

Sincerely,

Michael M. Hash
Deputy Administrator

Mr. GANSKE. So let's just be straight. You do not know whether they have been answered.

Mr. HASH. I do not know the status of that correspondence. No, sir, I do not.

Mr. GANSKE. And if they had not been answered, would that be an egregious error?

Mr. HASH. It would have been an inappropriate response definitely.

Mr. GANSKE. I mean this goes back to December 2, 1998, within the comment period.

Mr. HASH. I cannot defend—

Mr. GANSKE. Let's just assume that they were not answered.

Mr. HASH. I would prefer not to assume that, Dr. Ganske.

Mr. GANSKE. Okay. Well, we have no record that they were answered.

Mr. HASH. I will be happy to furnish you a record as we have it and if we have not answered those letters, we will do so promptly.

Mr. BILIRAKIS. The gentleman's time has expired.

Michael, if the gentlelady who is next would be considerate here, let me ask you. A couple of times at least you have made the comments that there are certain things that BBA will now allow you to do. But I would think that for instance, the reimbursements to managed care—which has resulted in an awful lot of Medicare beneficiaries losing those options and that sort of thing, you know what the intent of the Congress was. You have interpreted it a different way. So maybe you had the right to do that.

But the fact of the matter is we are all supposedly trying to get things worked out here. If there is certain language in BBA 1997 that needs to be changed in order to afford you the flexibility to be able to make some of these changes, why haven't you communicated that to us? I get the impression that HCFA is not trying to work with the Congress in terms of making some of these changes.

Mr. HASH. Mr. Chairman, I regret that impression because the kinds of things I outlined in my opening statement are reflective of our attempt to respond in a constructive way.

Mr. BILIRAKIS. I know but I mean in terms of what we can do. You have shared with us what your attempts are but in terms of what we can do in order to try to get these things worked out.

Mr. HASH. I think that is part and parcel of our offer to sit down and there has not been an opportunity to actually legislate up until now. There have been no proposals moving forward that I am aware of, but we are certainly at a place where we would like to work with you to fashion proposals.

And a part of that process would be the identification of statutory changes that would either extend greater flexibility to us so that we could exercise discretion and judgment or, in fact, if the agreement is that it needs to be more direct in terms of the statutory language, we also would be prepared to recommend where that should be the case.

Mr. BILIRAKIS. Okay. Hopefully we can do that together on a bipartisan basis.

Ms. Eshoo, thank you for your indulgence.

Ms. ESHOO. Absolutely. You can count on it.

Mr. Hash, it is always a privilege to have you here to give forthright, solid testimony. You take shots well and you do your best to answer our questions directly and I appreciate that. I think we should all acknowledge in this room that we all have kind of tough jobs but that we like them, too. No one twisted our arms off to do it, each one of us.

Mr. HASH. Absolutely.

Ms. ESHOO. So we are burdened but we are privileged, as well.

As you know, in 1996 the Congress passed and the President signed into law the FDA Modernization Act to streamline the FDA approval process. I was very proud to be the Democratic sponsor of that bill. It was not an easy bill to get through the Congress but we did. And what I am really pleased about are the reports that I get from both the biotech and the medical device people, both in my district and across the country, telling me that FDA is approving the new technologies and the life-saving drugs and the devices that bring about the changes faster than ever before. So that is on the plus side.

They also tell me that they still cannot get their products to patients and this is disturbing to me. People may be thinking, well, why is she raising this? It was her bill. That is why she is raising it during this hearing. But it was directed toward obviously both saving money with better technologies and saving money in areas that were invasive, longer stays, et cetera, et cetera. I wanted to get that down for the record.

Now since there are these complaints about getting the products to patients and HCFA's role in this, can you tell me what you are doing administratively to streamline the process of assigning medical procedure codes and classifying new technologies and updating the payment levels?

And as a follow-up question, it is also my understanding that because of Y2K concerns that HCFA has stopped assigning new procedure codes until after January 1. Is this so and if it is, what impact do you think this will have on Medicare beneficiaries' access to new technologies?

Mr. HASH. Let me take the first part of that question, if I may.

With respect to what we are doing to ensure that advancements in health care and certainly in pharmaceuticals and devices are brought to the bedside or the care side of our beneficiaries, we have launched a very bold, new coverage process, decisionmaking process at HCFA because we, too, have felt that the importance of these advancements being made available under our coverage policy as rapidly as possible is an extremely high priority for us.

As a result, you may be aware we have instituted a new coverage decisionmaking process. It is actually modeled, in many respects, after the FDA process for approval. It has a very open and transparent and time-limited review cycle for applications for Medicare coverage. It involves the establishment—

Ms. ESHOO. When was it launched?

Mr. HASH. It was launched the first of July 1999. We published the process itself this spring in the Federal Register and it became effective on the first of July.

And as a part of that, we put into place what we call a coverage advisory committee, which is composed of 125 imminent scientists and practitioners from around the country, to function in much the way that the FDA advisory councils function, where subsets of that advisory committee will be asked to——

Ms. ESHOO. That is good news. There are many members of this subcommittee that worked on the FDA reform on both sides of the aisle.

Let me ask you this. In what you have launched, and you term it as being bold, is there anything that is part of this policy or internal administratively where you are going to sit down and review the effectiveness of what you have launched?

Mr. HASH. Absolutely.

Ms. ESHOO. So that you can track these timeframes and maybe give a report back to us?

Mr. HASH. Absolutely. In fact, we are putting up on our website the receipt date of applications for coverage process. People can track, on that website, where it has been assigned, what its due date is, what its status is, whether it has been referred to the advisory committee, or whether a decision can be made without that. In many cases, we expect to clear these applications within 90 days of the origination of the application.

Ms. ESHOO. And the reimbursement codes are attached to this?

Mr. HASH. Well, the first step is the coverage itself and then, as you know, we rely on the codes through a system that is established, in effect, by the AMA, the current procedural terminology.

In some cases, a new code must be developed for something for which there is not an existing code that is appropriate. That process can take some time. It is not a process that we run. It is run by clinicians who run the CPT editorial panel.

But nonetheless, we are definitely trying to work with them to make sure that our cycle gets the new coverage items into the CPT process as quickly as possible.

Ms. ESHOO. Mr. Chairman, could I ask for your consideration for Mr. Hash to answer my second question if he can briefly?

Mr. BILIRAKIS. Without objection.

Ms. ESHOO. Thank you.

Mr. HASH. Our outside contractors on Y2K advised us that in order to make sure we could do recertification of the readiness of our claims processing systems, that we should not make any systems changes between the period of October 1 until we can ensure our systems are compliant after the millennium rollover.

Ms. ESHOO. So you have stopped issuing new procedure codes?

Mr. HASH. Well, people can still get a new procedure code and bill but if it is not reflected in the current codes that are in our claims processing system, it would not be recognized.

Ms. ESHOO. Does that have anything to do with the payment level, though, what you have just described?

Mr. HASH. It could affect that but what I would like to do is if I may, I would like to have someone who could more knowledgeably explain exactly the relationship of our stand-down with respect to changes in our claims processing and how that affects the recognition of new codes between now and after the new year.

Ms. ESHOO. I think everyone is sufficiently Y2K'd out in the country. It is this term. My mother keeps saying to me, "What does that mean?" But at any rate it does have something to do with the underlying, I think, the underlying reason for today's hearing. It is a contributor to it.

So I will look forward to getting—

Mr. BILIRAKIS. And we will continue to—believe me, this is not it. We will continue and hopefully—

Mr. HASH. I would like to follow up with you, if I may.

Ms. ESHOO. I would be delighted. Thank you very much.

Mr. BILIRAKIS. Mr. Bryant will inquire.

Mr. BRYANT. Thank you, Mr. Chairman. Thank you, Mr. Hash, for being here. I have a number of questions so if you could keep your answers as brief as possible. And in the event I do not get as complete answers as you want to give or you do not respond to all of them, could you furnish me an answer in writing afterwards?

Mr. HASH. I would be happy to.

Mr. BRYANT. Let me follow up very quickly with Dr. Ganske's question, an area that I have an interest in, about the SGRs. My understanding is that the BBA requires you to publish for the year 2000 this SGR for physician services by August 1, and we are beyond that now. I understand that has to be used in this next fiscal year.

Where are we on that and when might we see this notice published?

Mr. HASH. My understanding is I believe that that is a part of a regulation that we are publishing on the physician fee schedule, which is due out at the end of October, which again the statute requires publication 60 days in advance of the year in which it applies. That is my understanding.

If I am not correct about that, I want to get back to you, but I think it is a part of that rulemaking that is going forward now.

Mr. BRYANT. It is not going to be ready, is it, by the beginning of—

Mr. HASH. I am correct that it actually is going to be a separate notice from the October physician regulation and that it is currently in clearance in our department and we expect to publish it shortly, meaning within the next week or 2, I believe.

Mr. BRYANT. Let me move on. I am again bouncing from subject to subject here.

In the area of what Medicare has traditionally covered, the administration of medications, infusions, injections in an office visit, Medicare, according to some sources, appears to be changing its policy so that none of the medications will be covered if there is a possibility that it could be self-administered by a patient, regardless of how frail that patient might be.

Is that true? Is Medicare changing its policy on covering these drugs that could be administered in a physician's office? And if so, briefly why?

Mr. HASH. We are working on a regulation to clarify the statutory admonition, which is that outpatient drugs are excluded from Medicare coverage when they, in fact, are self-administered.

There is, we believe, reason to believe we have not been as clear or precise as we should be about what those conditions are and

how we make those distinctions about what is self-administered and what is not, and we expect to publish a regulation, a proposed regulation for comment this fall.

Mr. BRYANT. Okay, I think that will be sufficient.

Regarding telemedicine, our Governors just had a conference of southern Governors in Tennessee and that has been one of the topics. Certainly I have seen some issues where HCFA has had, I believe, narrow interpretations that I believe in the long run are going to stifle or chill the growth of this technology, telemedicine, regarding the occurrence of consultation in real-time, who is a presenting practitioner, the definition, and those kinds of things.

And again I would urge HCFA to look at these issues so that we can, particularly in rural areas across the country, take advantage of this new technology.

Mr. HASH. Let me assure you that we are doing that. You may recall that Secretary Shalala wrote a letter to the Congress in which she identified four issues that had been raised in the telemedicine arena, a couple of which you just mentioned, and that she directed the department to make a review of that and that basically has fallen to HCFA's responsibility.

We are reviewing those issues and we are going to be issuing a report on our analysis and recommendations with regard to those four issues that are in the secretary's letter.

Mr. BRYANT. In regard to nursing homes, I had occasion to visit those, also, and one complaint was the \$1,500 cap on therapy, as opposed to hospitals not having the cap. Do you see any change there? Do you think that might be appropriate to reconsider? That was a serious concern.

Mr. HASH. I think it is fair to say that as we have looked across the issues that have been raised about BBA impacts, the therapy caps has been among those at the top of the list in terms of the evidence that is out there that there may be an inadequate opportunity for rehabilitation therapies in general to be made available to patients, particularly in the nursing home setting. And that is an issue that we want to work with you on in terms of a Medicare reform proposal.

As you may know, this provision got added to the BBA at the very end. It was not one which we recommended. I think when it got extended to cover all settings except hospital outpatient departments, it took on a cast that perhaps has created unintended consequences and we would like to work with you on that.

Mr. BRYANT. If I might ask you quickly to respond in writing to one final question in terms of the winners and losers in any kind of implementation of a new payment system, we have heard a lot, and I know we heard a lot in the districts about people who perceive themselves as losing in this.

On the other side, can you identify, again in late-filed testimony, the groups who will benefit from this new system and explain why their reimbursement rates would go up?

Mr. HASH. Are you referring to hospital outpatient payments or all—

Mr. BRYANT. APCs.

Mr. HASH. Right, yes, sir.

Mr. BRYANT. Thank you.

Mr. BILIRAKIS. In the letter that you refer to from Secretary Shalala, would you please submit that as part of the record?

Mr. HASH. I would be happy to, Mr. Chairman.

Mr. BILIRAKIS. Without objection, it will be included in the record. Thank you very much.

[The letter from Secretary Shalala follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF HEALTH AND HUMAN SERVICES
November 9, 1999

The Honorable KENT CONRAD
United States Senate
Washington, D.C. 20510

DEAR SENATOR CONRAD: I am pleased to inform you and the members of the Rural Health Care Coalition that the final rule implementing Medicare payment for teleconsultation in rural health professional shortage areas will be published on November 2. The Department of Health and Human Services believes that telemedicine has potential for extending access to medical care to beneficiaries located in rural and medically isolated areas and we are pleased that this rule, reflecting the statutory changes made by the Balanced Budget Act of 1997 (BBA), will expand coverage for telemedicine.

Payment for teleconsultation represents a significant improvement over traditional Medicare policy for rural areas by allowing payment for a service that historically has required a face-to-face, "hands on" encounter. This rule is a first step in refining face-to-face requirements for a medical service under Medicare to accommodate telemedicine services. We are open to developing modifications to Medicare telemedicine coverage and payment policies as the law permits and as more program experience in this area is obtained. We have identified several issues related to teleconsulting that we will need to address further. We will send recommendations to Congress in a year.

This final rule implements the changes in telemedicine eligibility, coverage, and conditions of Medicare payment made by the BBA. First, in accordance with the BBA, the rule implementing payment for teleconsultation specifies that eligibility for teleconsultation is limited to rural health professional shortage areas. We have interpreted the definition of a health professional shortage area broadly to include both full and partial county rural health professional shortage areas and to consider the site of presentation, that is, where the beneficiary is physically located during the consultation, in determining eligibility for teleconsultation.

The rule also indicates that the scope of covered services is consultation services for which payment may be made under Medicare. These services include: office or other outpatient consultations; initial and follow-up inpatient consultations; and confirmatory consultations.

The rule implements the statutory provision for Medicare payment for a consultation service that is delivered via telecommunications systems. As a condition of payment, the patient must be present and the teleconsultation must involve the participation of the referring practitioner, or a practitioner eligible to be a referring practitioner who is an employee of the actual referring practitioner, as appropriate to the medical needs of the beneficiary.

Additionally, under the regulation, the technology used to deliver a teleconsultation must allow the consultant to conduct an examination of the patient in "real time," using interactive audio and video telecommunications equipment. The requirement that the patient be present, a presentation practitioner participate, and interactive audio and video equipment be used is a substitute for a face-to-face examination which is a coverage requirement for consultation under Medicare. Note that the "real time" requirement, needed to permit interaction of patient and consultant, does not require use of high-end, full motion interactive video equipment; less expensive technologies may permit "real time" examination. The requirement, however, would not allow payment for a teleconsultation when traditional store-and-forward technology is used.

The rule also implements the statutory provision that the payment must be shared between the referring and consulting practitioner, and that payment must not exceed the current fee schedule of the consultant. The rule specifies that the consulting practitioner will receive 75 percent and the referring practitioner will receive 25 percent of the consultant's fee schedule amount. The geographic practice cost index applicable to the location of the consulting practitioner will be used for

pricing teleconsultation claims. By using the consultant's location for pricing claims, the payment amount for teleconsultation will be the highest allowed by the statute.

We recognize that we will need to address certain issues you and your colleagues have raised as we move forward to further develop Medicare telemedicine policy. Congress and the Administration must have a clearer picture of the policy and financial implications of several issues related to teleconsultation including: (1) the use of store-and-forward technologies used as a method for delivering medical services; (2) the use of registered nurses and other medical professionals not recognized as practitioners under Medicare to present the patient to the consulting practitioner; and (3) the appropriateness of current consultation codes for reporting consultations delivered via communications systems. Below is a brief discussion of these issues:

- In exploring the use of store-and-forward technology, our primary objective will be to determine if or when, store-and-forward technologies permit delivery of a medical service that warrants a separate and distinct payment from Medicare. As mentioned above, Medicare does not make separate payment for the review of a previous medical examination. Program integrity implications of moving in this direction may be significant. Additionally, specific attention will be given to how store-and-forward technology is being used in dermatology.
- With regard to the practitioners who may be eligible to present the patient to the consultant, we will examine the circumstances in which a registered nurse, licensed practical nurse, or other medical professional who is not recognized as a practitioner under Medicare may have the qualifications to present the patient to the consultant.
- Finally, we recognize that the current coding structure for consultation services may not be appropriate for reporting some forms of teleconsultation. We will examine the possibility of expanding the scope of coverage under telemedicine to include additional existing services that are consultative in nature, and the development of new codes to identify services specific to telehealth.

In a year, we will send recommendations to Congress regarding these issues. We look forward to working with you in providing increased medical access for Medicare beneficiaries through the use of telemedicine. A similar letter has been sent to the other members who cosigned your letter.

Sincerely,

DONNA E. SHALALA

Mr. BILIRAKIS. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. Like everyone, I would like to thank Mr. Hash for being here.

Under HCFA's proposed rule on hospital outpatient prospective payment system, you propose to reimburse new cancer drugs, which is anything after 1996, at the lowest APC rate, which is \$59.13.

In my opening statement I am sure you heard that I am concerned that if implemented, this proposal would have a crippling impact on cancer care and would essentially stop the development of new drugs. And what company would invest its resources in a drug that would be reimbursed at such a low level, especially when they take into consideration this lower reimbursement rate is locked in for well over half the cancer patients in the population?

First of all, why was the decision made to place all new, innovative drugs in the lowest payment category?

Mr. HASH. Well, let me just say the issue for us now, Mr. Green, is that we are equally concerned about the impact of the outpatient prospective payment system proposal on cancer drugs, or cancer therapy with chemotherapy agents. And as you know and have mentioned in your statement, we are actively engaged in reviewing the comments that we have received on this. We intend to address many of these issues in the final rule that we will publish at the end of this year.

I want to assure you that it is also a serious concern of ours and our commitment is that we want to make sure that this system in

no way presents any barriers for appropriate cancer care for any of our beneficiaries.

With respect to the specifics in the proposed rule last September, I think all of us recognize that in the area of drugs that the data that were available to us to develop a hospital outpatient prospective payment system were not adequate. Therefore, we have contracted with an outside contractor for the purpose of surveying, in particular, cancer and other high-cost and often infrequently used drugs so that we have a much richer and better data base on the cost of drugs that are now on the market.

We expect to use that information to inform the revisions to our process in the regulation.

Mr. GREEN. The second part of that is what impact does HCFA believe placing these therapies in the lowest payment category have on utilization, as well as on future research and development? And also I guess these rates, the impact on the 10 free-standing cancer centers we have in our country. One of them is in Houston but also Sloan-Kettering and the Cleveland Clinic.

Mr. HASH. Well, let me again say the reason we publish proposed rules is so that we can get comment and advice about how we can make it better and, in this area, we intend to make it better. And I do not want to defend the particular aspects of the proposed rule because we put it out there to the best that we could, based on the data that we had, but we are struggling to get a better sense of this particular issue so that our final rule takes that into account.

As you know, even in the proposed rule—and this is not widely understood—we are actually proposing to separate in this system the payment for the drug itself and the payment for the administration. So, if an individual comes in, is administered a chemotherapy agent in a hospital outpatient clinic, there is an administration APC for billing purposes.

Depending on what the drug is, in the initial proposal we created four separate categories for chemotherapy drugs. We are obviously reviewing that issue based on the comments, to make sure that we adequately reflect the costs of the drugs that are now in use.

Mr. GREEN. We know that a doctor's recommendation or opinion are the No. 1 reason why patients are seen and receive a certain type of treatment like cancer screening or a particular treatment or therapy. And while I think we all agree that reimbursement levels should never influence a provider's decision to recommend one treatment over another, I am concerned that if the hospital outpatient PPS is implemented as proposed, there will be no way that we can avoid this problem. Do you agree or do you have a comment?

Mr. HASH. I think, in our final rule, we do not want that to be a consequence of the new payment system. What we are trying to do is to put together groupings of related services in order to create prospective payments that provide an incentive, not only for access to the best and most appropriate therapy, but for health care providers to provide their care in the most efficient and economical way possible.

Obviously, as someone mentioned earlier, we are trying to find the right balance between incentives for efficiency and economy

and the appropriate assurance of access to covered services for our beneficiaries.

Mr. GREEN. I notice in your statement where you said HCFA, you are looking at the 3-year budget to make it budget-neutral. Does HCFA have the authority to phase the PPS in over 3 years and make it budget-neutral?

Mr. HASH. We do believe that we could have a transition on a budget-neutral basis in implementing the hospital outpatient payment system.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Greenwood will inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I want to raise a question or an issue that is not directly related to the Balanced Budget Act which is crucial to Pennsylvania's hospitals, and that is the disproportionate share issue that is, I think, unique to Pennsylvania.

Since 1986 Pennsylvania hospitals were able—in fact, the FIS, fiscal intermediaries, assembled the data to count general assistance days toward the DSH payments for Pennsylvania hospitals and, as you know, last year HCFA decided that not only was that not going to continue forward but that, in fact, HCFA was going to go back and collect from all of these hospitals. It was a tremendous blow. I think the number is on the order of magnitude of \$200 million in Pennsylvania.

Several of us, Chairman Thomas and myself, have raised this as an issue of concern and I would like to understand your position on that.

Mr. HASH. Yes, sir. Mr. Greenwood, this has been an extraordinarily difficult issue for us. Obviously it, I believe, arises from a failure on the part of our contractor to apply appropriately the statute and regulations in this area. I believe that our review of the formula that is in the law for determining Medicare DSH payments makes it very clear that for purposes of hospital days that are to be included in this calculation, it is days associated with individuals entitled to benefits under Medicaid, Title XIX of the Social Security Act.

Unfortunately, in the case of Pennsylvania, the State seems to be reporting to the fiscal intermediary data that put together not only Medicaid days but also days associated with patients that were eligible for a general assistance program in Pennsylvania. That commingling of the days produced a larger disproportionate share adjustment than would be authorized under the statute if it did not include those general assistance days.

And under the law, we believe that we did not have any choice but to collect overpayments that were made in error in regard to the inclusion of these inappropriately covered days.

Mr. GREENWOOD. Well, is that your conclusion? Is that HCFA's conclusion, that you do not have the statutory authority to—

Mr. HASH. Yes, sir, that is our conclusion. And my understanding is the fiscal intermediaries that serve those hospitals have already initiated the process of recovery and that it is ongoing.

Mr. GREENWOOD. That is very much the case, with devastating consequences. Do you have a position on whether you would like the statute changed so that you can right this wrong?

Mr. HASH. I think actually that is a matter we should discuss. I think the reasons behind the statute having been written the way it was, presumably at some point people believed that the disproportionate share adjustment in Medicare should be limited to the fraction of days for low-income patients and the proxy for low income was Medicaid-eligible individuals. If people want to enlarge that proxy—

Mr. GREENWOOD. No, I do not think that is the question, sir. Sorry for interrupting you. I think Pennsylvania hospitals are content with the notion that forward, looking forward, those days will not be counted anymore. The hard part is going back and hitting hospitals that are, in fact, very strapped because of BBA issues and hitting them again with this double whammy is tough. And we are going to pursue giving you the authority to at least not have to go back and get those payments.

Let me quickly turn to an issue that is close to that raised by Mr. Green, and that is the exempt cancer centers, including Fox Chase, which is in my area, serves my area.

Under the Balanced Budget Act, we directed HCFA to consider establishing a separate payment methodology that recognizes the special mission of these centers. My understanding is that HCFA has declined to do that, not to consider but to, in fact, come up with a separate payment methodology.

And it is my belief that these cancer centers, including Fox Chase, are being hammered and are losing significant dollars and are threatened by this outcome. Could you discuss HCFA's thinking in this regard?

Mr. HASH. We have not reached a final judgment on that question because that will be part of the final rulemaking for the hospital outpatient prospective payment system.

We are very much aware of the concerns of cancer centers. There are 10 of them around the country. And obviously the Congress, as you pointed out, identified some special authority for treatment of them and we are continuing to review that question. We have not made our final decisions on it.

One of the things, again, that may have been somewhat misleading is that the impact assessments that went out with the proposed rule indicated a very large impact on cancer hospitals. We think that, in part, stems, again, from data problems in that, in some cases, people may have billed for cancer treatments with the drug and the administrative costs together, as opposed to separately. The data we have may not have broken it out properly.

Under the proposed rule, we, as I mentioned a moment ago, proposed to pay separately for administration and separately for the drug and separately for each dose of drug that is administered. We want to make sure, through additional efforts on the data side, that we, in fact, have a better assessment of the impact of this proposal on cancer centers.

But I want you to know that we do not intend to disadvantage and cause those centers not to be able to provide the valuable service they are providing to patients who require cancer treatment.

Mr. GREENWOOD. Thank you.

Mr. BILIRAKIS. Miss Capps to inquire.

Ms. CAPPS. Thank you. I want to thank Mr. Hash for being here today. I appreciate your testimony.

You spoke earlier about some of the steps that HCFA has taken or will take to lessen the impact of the cuts on small rural hospitals and I am hoping that in the next couple of minutes you can elaborate a little bit on this.

Most specifically, we have been hearing so many negative projections about the proposed hospital outpatient PPS, prospective payment system, that it is easy to forget that this change is a very pro-consumer provision. Under the current system, seniors end up paying about 50 percent of the total bill and for most other parts of the Part B benefits the co-pay is around 20 percent. And could you remind our committee of the disadvantages of this current system and how the proposed payment system will take effect?

Mr. HASH. I would be happy to, Ms. Capps.

Briefly, as many of you know, historically beneficiaries have paid coinsurance for their hospital outpatient services on the basis of the hospital charge, which was on a charge schedule at the time they received those services. That charge does not necessarily bear any relationship to what the program ultimately determines is the appropriate amount for the service.

What the BBA changes enable us to do, is to bring those beneficiary coinsurance payments into line with 20 percent of the Medicare payment amount, which was the intention and certainly the statutory provision. Up until now, beneficiaries have been subject to a coinsurance that was based on hospital charges that were raised very dramatically over time. This resulted in some of those copayments equalling as much as 50 percent or even more of the payment that was made to the hospital for those services. The BBA fixes that.

Ms. CAPPS. And could I also mention that the AARP has written a letter to the speaker, which I would like to submit a copy of this letter for the record?

Mr. BILIRAKIS. Without objection.

[The letter follows:]



Attn: Karen

August 12, 1999

The Honorable J. Dennis Hastert
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

The Balanced Budget Act (BBA) of 1997 corrected a flaw in the calculation of beneficiary coinsurance for hospital outpatient services. For years, Medicare beneficiaries were forced to pay significantly higher coinsurance for hospital outpatient services than for other Part B services. In fact, in recent years, many beneficiaries have paid as much as 50 percent of the total payment to hospitals for outpatient services through their coinsurance. The BBA began to address this problem by slowly phasing coinsurance back down to the correct level of 20 percent of the total payment to hospitals.

We understand that concerns are now being raised about how the outpatient prospective payment system and the coinsurance correction are being implemented. AARP believes that before Congress makes changes to the BBA provision or HCFA undertakes an administrative change, there needs to be a thorough examination of the issues and the implications, including an understanding of what revisions in the policy would mean for beneficiaries' outpatient coinsurance and their Part B premium.

For instance, we believe it is important to consider whether the changes under consideration would require beneficiaries to pay a higher monthly Part B premium. Beneficiaries' Part B premium is already projected to nearly double from \$45.50 a month in 1999 to \$84.60 by 2008. A significant proportion of this increase is attributable to the changes made by the BBA. Since the amount of a beneficiary's monthly premium is directly tied to the level of Part B spending, and hospital outpatient services are paid out of the Part B Trust Fund, beneficiaries' premiums will rise if Medicare increases payments for outpatient services.

Beneficiaries would also be adversely affected if the implementation of the new outpatient prospective payment system (PPS) was delayed. A delay in outpatient PPS and the coinsurance "fix" would force beneficiaries to continue to pay increasingly higher coinsurance rates for outpatient services. In addition, if a delay in PPS resulted in higher Part B spending for outpatient services, the beneficiary premium could also rise.

601 E Street, NW Washington, DC 20049 (202) 434-2277 www.aarp.org
Joseph S. Perkins President Horace R. Deen Executive Director



Page Two

Correcting the inequity in beneficiary coinsurance for outpatient services remains a high priority for AARP and our members. For years, beneficiaries have been subject to an unfairly high coinsurance for outpatient services. A very slow correction for this inequity was put into place by the BBA. New changes should not delay the coinsurance correction further or ask beneficiaries to pay instead through increases in their Part B premium. Therefore, we urge Members of Congress to carefully weigh all of the implications of making changes to the BBA outpatient coinsurance provision. If changes are made, then the impact on beneficiary coinsurance and/or premiums must be clearly understood.

If you have any questions, please feel free to call me directly or have your staff contact Tricia Smith or Kirsten Sloan of our Federal Affairs staff at (202) 434-3770.

Sincerely,



Horace B. Deets

cc: Michael Hash, HCFA Deputy Administrator



Bringing lifetimes of experience and leadership to serve all generations.

How the "Glitch" in Medicare Hospital Outpatient Coinsurance Directly Affects Beneficiaries

When it comes to most hospital outpatient services, Medicare beneficiaries pay significantly more than the usual 20% coinsurance. In fact, beneficiaries pay, on average, 47% of what the hospital actually is paid (by Medicare and the beneficiary) for the service. A "glitch" in the law allows hospitals to shift costs by charging beneficiaries more than 20% of what Medicare determines is a reasonable amount for a service. Here is a real case example of how this can affect the average beneficiary.

Medicare beneficiary Jeanette D. of Santa Teresa, New Mexico had surgery performed in a hospital outpatient department. The hospital charged \$6,275.53 for the procedure (See #1, Form 1). Jeanette's Explanation of Medicare Benefits (BOMB) form indicated that she owed \$1,255.11 in coinsurance (See #2, Form 1). The remaining balance of the charges was \$5,020.42 (See #3, Form 1), yet the hospital bill indicated that Medicare paid only \$815.81 (See #4, Form 2). Since the hospital agreed to accept assignment, it did not attempt to collect the remaining \$4,204.61 (See #5, Form 2).

Jeanette's coinsurance for the procedure was not based on Medicare's approved payment of \$815.81. Instead, it was based on the total \$6,275.53 charged by the hospital. As a result, Jeanette's "20%" coinsurance totaled \$1,255.11 — 20% of what the hospital charged and 61% of what the hospital was actually paid for the procedure.

This is only one of the thousands of cases where Medicare beneficiaries pay significantly more than the typical 20% coinsurance for hospital outpatient services. The irony is that many older Americans believe that services performed in hospital outpatient departments are more cost-effective than inpatient services — yet beneficiaries end up paying more out-of-pocket as outpatients than they would if they had stayed in the hospital.

Because of the increasing number of beneficiaries who receive services in hospital outpatient departments, the inequity in the coinsurance has become a widespread problem. As hospitals continue to increase their charges, the amount that beneficiaries pay in coinsurance will continue to skyrocket.

AARP Federal Affairs
6/2/97

American Association of Retired Persons 601 E Street, NW Washington, DC 20049 (202) 434-2277

Margaret A. Dixon, Ed.D. *President*

Horace B. Deets *Executive Director*

Some argue that this really isn't a direct out-of-pocket cost because most Medicare beneficiaries have Medigap coverage. While most beneficiaries have some form of supplemental coverage, this glitch in the law should not result in beneficiaries being pushed into the Medigap market as a way of finding relief from exorbitant outpatient costs. Moreover, even with supplemental coverage, beneficiaries are still vulnerable to greater costs passed directly on to them through higher Medigap premiums. A portion of the increase in 1996 premiums for some supplemental plans was directly attributable to rising outpatient costs.

Key to Attachments

To further illustrate Jeanette's case, copies of the Explanation of Medicare Benefits (EOMB) and the bill submitted by the hospital are attached. The numbers on the forms correspond to the information provided below.

- #1 \$6,275.53 – The hospital's total charge for the procedure
- #2 -\$1,255.11 – 20% of the hospital's charge/Jeanette's coinsurance
- #3 \$5,020.42 – The remaining balance of the charges
- #4 \$815.81 – Medicare's actual payment amount
- #5 \$4,204.61 – Amount the hospital wrote off on the basis of accepting Medicare assignment

\$1,255.11 – Jeanette's coinsurance: 61% of the total payment

\$ 815.81 – Medicare's payment: 39% of the total payment

\$2,070.92 – Total payment to hospital

6 EXPLANATION OF MEDICARE BENEFITS (GOMB) FORM

THE HOSPITAL

Ms. CAPPS. Thank you. Asking that the BBA reforms not delay this transition to 20 percent and maybe you could speak even further about how delaying it, how it is going to affect seniors.

Mr. HASH. Well, I think it is clear that hospital charges for outpatient services are likely to continue to rise for a number of reasons that have been talked about already here today. So, as we continue to delay implementation, those coinsurance payments continue to go up. We would like to bring that into line as quickly as possible.

Ms. CAPPS. And if I have a little bit more time, back to my original question. You, in a broad way, outlined some of the steps that you are taking to lessen the impact of cuts to small, rural hospitals. My district is going to be listening for your elaboration in the remaining time on how this is going to happen.

Mr. HASH. Let me just quickly tick off the things I mentioned somewhat briefly earlier. We are delaying the expansion of the hospital transfer policy, which has been applied to 10 DRGs, but was scheduled to be applied more broadly. We have delayed that, which will be of benefit, I think, not only to rural but to other hospitals, we well.

We talked about the transition, on a budget-neutral basis to the implementation of the hospital outpatient prospective payment system. We have talked about delaying what is called the "volume control mechanism," which is referred to in the BBA as basically an annual target to be applied to the growth in hospital outpatient payments. We have decided to suspend imposing that target growth rate for the first few years of the PPS.

We also have committed ourselves to changing the criteria that allows rural hospitals to qualify for use of the urban hospital index, which has the effect of increasing Medicare payments to those rural hospitals. And we have talked about using the hospital wage index to adjust payments under the hospital outpatient prospective payment system from year to year.

I think those changes, combined with the President's setting aside of this fund, the \$7.5 billion, to smooth out any unintended consequences of the BBA, represent real acknowledgement of the importance of supporting rural hospital providers and all providers who are low-volume providers.

Ms. CAPPS. When I go back home, how soon can we begin to see this? I do not think it has registered yet, at least among the hospitals that I am in touch with.

Mr. HASH. Well, many of the things I mentioned are associated with implementation of the outpatient prospective payment system, which, of course, has not occurred yet. So these will be associated with that process, which will come later next year. The wage index change is being put into place right away, so we are getting ready to publish the new criteria for that so that there will be an easier opportunity for hospitals in rural areas to qualify for a more favorable wage adjustment.

Ms. CAPPS. Thank you.

Mr. BILIRAKIS. Mr. Deal to inquire.

Mr. DEAL. Thank you, Mr. Chairman.

In your prepared statement you indicate that the solvency for the Medicare Trust Fund is projected to be 2015, which is one of the more optimistic out-years that I have seen projected.

You also indicate that the President's proposal in the 2000 budget would ask for a \$7.5 billion infusion of money from the surplus, the anticipated surplus. I have several questions in that regard.

The 2015 insolvency date, is that the projected date without any other additional infusion and without any other statutory changes to the current system?

Mr. HASH. Yes, sir. That is a projection actually that is made on behalf of the trustees of the Medicare Trust Fund. It is their estimate, which is calculated by the actuary, the Office of the Actuary at the Health Care Financing Administration.

Mr. DEAL. Do you know the either daily, monthly or annual deficit is at the current time?

Mr. HASH. I do not have it with me, but I do know that it exists and is readily accessible and I would be happy to furnish it to you.

Mr. DEAL. And I believe that projection for that deficit will increase significantly after about the year 2010?

Mr. HASH. I wish I had the figures here. My recollection is that the deficit does appear sometime, under current assumptions, after 2010. I just do not have the schedule in front of me.

Mr. DEAL. I recognize that questions about surplus have always been fluctuating figures. Is the \$7.5 billion proposal a one-shot infusion out of anticipated surplus for the year 2000?

Mr. HASH. I think the best way to answer that is that the \$7.5 billion is part of a broader comprehensive proposal that the President has put forward that involves not only the smooth-out of the BBA issues that we have been talking about this morning, but also the structural reforms to the Medicare program and, very importantly, the dedication of a significant portion of the surplus to the Medicare Trust Fund.

To answer it more specifically, the estimate of the \$7.5 billion was the effect of making changes that would actually affect years through 2001 to 2009. So it is an effect that is estimated over a 10-year period.

Mr. DEAL. So it is not just a one-shot infusion of supposedly surplus funds.

Mr. HASH. As you think about changing BBA policies that result in payment changes, those have ripple effects that carry on beyond the year in which they are made. And the \$7.5 billion is intended to be a fund that would cover the out-years, up to 10 years worth of out-years costs associated with whatever package of smooth-out changes to the BBA are agreed to by the Congress.

Mr. DEAL. And would the surplus funds be surplus from the income tax general revenue stream or would it require using the surplus from the Social Security Trust Fund?

Mr. HASH. These are actually—the \$7.5 billion is anticipated to be from what we refer to, I believe, as on-budget surpluses, which are surpluses generated without regard to surpluses in Social Security or Medicare trust funds.

Mr. DEAL. And that figure once again is over what period of time?

Mr. HASH. Ten years.

Mr. DEAL. So it would be \$7.5 billion over a 10-year period from anticipated surpluses.

Mr. HASH. That is correct, on-budget surpluses.

Mr. DEAL. Mr. Chairman, I would like to yield the remainder of my time to my colleague, Dr. Ganske.

Mr. GANSKE. Mr. Hash, I am very disturbed with the gist of some of your comments as it relates to the SGR. Basically when you talk about the gross domestic product component of this, as well as the percentage of recipients, of beneficiaries who are in managed care, you admit that you were off.

Mr. HASH. Those were errors.

Mr. GANSKE. Those were errors. I mean it is right there. You admit it. The facts are the facts.

Mr. HASH. I do, Dr. Ganske.

Mr. GANSKE. But then what you say is well, but we made an error, but even though this is a method of calculation for payment that is cumulative—in other words, if you make an error now and if it is not corrected, that compounds—sort of like compound interest—

Mr. HASH. That is correct.

Mr. GANSKE. That we are just going to let it go.

You know, I was one of the authors of this bill and we are in the process, the staff and I, of looking up the pertinent sections for this bill.

I believe you have the statutory authority to go back and fix that error, which you readily admit is an error. And we will provide you with the language on that. And I believe that this is more than just sloppy if you do not fix this.

And I want you to take a message to Secretary Shalala on this, a strong one, okay? If you make a mistake, own up and fix it but do not compound over the next 5 years the error. You have got statutory authority to fix an error. There is nothing in that statute that I know of that fixes an error in stone, and it should be done.

I do not think Congress has to pass a law on this. It is already in the statute.

Mr. BILIRAKIS. A very short response.

Mr. HASH. We intend to fix it and that is why the President's budget includes legislation to fix it. We do not want to leave it unaddressed and we intend to act on that, with the help of the Congress.

Mr. BILIRAKIS. The gentleman's time has expired.

Miss DeGette to inquire.

Ms. DEGETTE. Thank you, Mr. Chairman.

The first thing I want to talk to you about, Mr. Hash, is this example I used in my opening statement of the woman who is blind from diabetes and who is trying to keep her diabetes under control and now, under the Balanced Budget Act, she used to get home health care but now she cannot get someone to come and fill the syringes. She used to have a registered nurse and maybe she does not need a registered nurse but now she cannot get anybody.

And this leads to the obvious tension that we are all trying to grapple with here, which is on the one hand, you do not want to provide services that are not needed or provide people who are more qualified than not. On the other hand, what do we do about

people like this with a very real need for services who are slipping through the cracks?

I know you addressed the rehabilitation issue but this is sort of a different issue.

Mr. HASH. Well, the case you cited is an extraordinarily sympathetic one. I think all of us are struck by this. This is a situation that is most unfortunate and we should find a way to address it.

I would say, as you know, it does beg this larger question of exactly what are the terms for covering home health services. And up until now, the law has been pretty explicit—that it requires, among other things, that an individual needs a skilled level of service, and that has been defined as a registered nurse's skill level or a registered therapist's skill level.

That is not to say that people do not need other kinds of services that do not require that level of skill, but the benefit design currently does not speak to unskilled services as a basis for home health coverage under Medicare.

And it obviously, as we have looked at what has been going on in home care, one of the things that grew the most rapidly was the home health aide visits. It was not the RN visits or the therapist visits that were growing so rapidly. It was the home health aide visits. And the difficulty with that was that access to the aide coverage under the home health benefit is linked to the first-order question: Does the patient meet the need for a skilled level service? If they do, then they are also qualified for aide services, as well.

Ms. DEGETTE. Right. But this is what drives my constituents crazy about the government, is because it is sort of like Alice in Wonderland to them. Well, I need this but not that.

Now I understand that the home health care area was and still is probably the most rife area with fraud and abuse. On the other hand, in an effort to cut that down, what we are doing is for seemingly meaningless bureaucratic reasons to these constituents, we are cutting off very real services.

I wonder if HCFA has given any thought to how we can balance this out. As I said, this is an extremely sympathetic case. But it is not the only case. There are other examples.

Mr. HASH. I am sure you would appreciate that we are not in a position, I think, to say that we should supply aide services to people who could benefit from them, notwithstanding whether or not they qualify for a skilled service.

Ms. DEGETTE. So you do not think there is any solution to situations like this.

Mr. HASH. Well, I do not think within the current structure of the statute—

Ms. DEGETTE. I understand but part of the context of this hearing is how can we fix things.

Mr. HASH. Right. I think we could definitely talk about ways in which the statute might be changed.

Ms. DEGETTE. And does HCFA have any ideas on that?

Mr. HASH. Well, I do not have a proposal on that and, as you might know, there would be a significant cost associated with it and we would need to weigh that, along with the other priorities that need to be addressed or people want to address.

So I think that is obviously what makes this undertaking extraordinarily challenging.

Ms. DEGETTE. I agree.

The second question that is sort of related is this streamlined inherent reasonableness test in the balanced budget agreement. I am wondering if HCFA has any kind of standard that it is using to make sure that beneficiary access and quality of care are not compromised with these IR payment adjustments.

To give you an example, I have a letter from Congressman Weldon in front of me where he is talking about these diabetes strips, the reimbursement being cut by 10 percent and the effect that that has on patients.

Mr. HASH. We are taking a very careful approach to the use of the authority in the BBA on inherent reasonableness and we recognize that as we use that authority to make changes nationally that we need to have firm market pricing data available to base those decisions on. We are not moving forward until we have a better sense of market prices on issues before we make any changes like this.

But I would say to you that in many of these areas, and test strips is one of them, we had a report by the HHS Inspector General that we were significantly overpaying for those items. So, that is why it ended up being addressed as it did.

But again, I hasten to add that in order to exercise this authority appropriately, we need to make sure we have the data base upon which to judge what things are reasonably available for in the marketplace.

Ms. DEGETTE. Thank you.

Mr. BILIRAKIS. Mrs. Cubin to inquire.

Mrs. CUBIN. Thank you, Mr. Chairman.

I am somewhat confused but first I want to make the statement that I realize the focus of this hearing is on the Medicare fee-for-service policy changes that are contained in the BBA but since Wyoming even yet relies almost completely on fee-for-service, I think we have been affected in a much more devastating way than other States and other places with higher population.

In my State, if we lose one single doctor, that means hundreds or thousands of people do not have any access to health care at all.

I want to go back a little bit to—and by the way, thank you for all the cooperation that you have given us in working through these things and the questions you have answered so far.

I want to go back to Dr. Ganske's line of questioning a little bit. I do not understand why you need help from Congress to fix the mistakes that were made with the real GDP and the fee-for-service enrollment because one of the four items that you are allowed to use in these adjustments is the impact of changes in legislative or regulatory initiatives.

So it seems to me you have the ability to go back and correct the mistakes that have been made so this cumulative problem does not move forward. So please tell me why you think you need a legislative fix.

Mr. HASH. I would be glad to, and I am glad you raised it again because I want to emphasize a point I did not make to Dr. Ganske, which is that the errors he is referring to are projection errors.

They were made by the actuaries. I believe we have the finest, most professional, most independent actuaries and I know that these were errors that are attendant to the estimating process.

So it is not a case of being sloppy or intentionally——

Mrs. CUBIN. Nobody has a crystal ball.

Mr. HASH. Right. So I want to make it clear that I do not think there were intentional errors.

Mrs. CUBIN. I agree.

Mr. HASH. They were associated with the estimating process.

Second, we have carefully and thoroughly and, I would say, exhaustively tried to review the statute with our general counsel at HHS to determine whether or not the statutory language allows us to correct for projection errors. The opinion that we have been given is that the statute does not acknowledge the authority to make projection error corrections.

We would like to have that authority and have recommended it in the President's budget proposals that are pending here in the Congress now.

Mrs. CUBIN. So you do not think that your regulatory allowance, if you will—I do not see why it would not because projections, making those projections are what is allowed through the regulations that you adopted, as I understand it.

Mr. HASH. But the statute requires that projections be made by the actuary on the factors that Dr. Ganske raised and those are not a part of the rulemaking regulatory process. We have not promulgated a rule that projects either enrollment in managed care plans, which is one of the issues, or in the growth in the GDP, which is the other issue he cited.

These are reserved to the province of the independent actuaries to make these projections. If they, in fact, make errors, we want to be able to correct them. And they are going to make errors and the errors are going to be in both directions, I might add. It is equally possible—in fact, it has occurred in the past where we have underestimated effects and that we have not gone back and tried to take money back from people as a result of that.

But I think the important point here is that we want to make the change. We want to correct the error and not have it ripple forward to all the SGRs of the future.

Mrs. CUBIN. Well, thank you. At least now I understand what the thinking is and I did not understand that at all.

Mr. HASH. We would welcome Dr. Ganske's support and your support to have the authority put into the law in upcoming legislation.

Mrs. CUBIN. I am glad that I am married to a doctor and not a lawyer because this just seems like such a nit-picky thing, that because this is projections, we cannot use the legislative language because I believe very strongly that was the legislative intent.

Mr. HASH. I understand.

Mrs. CUBIN. Then I want to just ask another thing as far as implementation of this goes.

Mr. BILIRAKIS. If you can do it really quickly.

Mrs. CUBIN. I can. It has to do with HCFA not yet having begun the refinement that was mandated by Congress on the practice expense values and the regulation or the proposed regulation not al-

lowing staff of practitioners who provide the major part of their service in a hospital but the staff in their office, not allowing that to be included in the practice expense values.

Mr. BILIRAKIS. That is an area—I am sorry; I did not mean to interrupt.

Mrs. CUBIN. Go ahead.

Mr. BILIRAKIS. I was just going to say it is something we want to continue to look at. Do you have a very brief—

Mr. HASH. I have a very short answer, which is that was in the proposed rule, Mrs. Cubin, and we are in the process of finalizing the rule. We have not made our final decisions and that is an issue we are familiar with and we have it under review and we intend to address it in the final rule.

Mr. BILIRAKIS. But are you in the process of doing that, going to take into consideration the additional data that has been submitted by, I believe, the AMA? Because if they sent out a survey and gotten additional responses and my understanding is that you, HCFA, may not be planning to take into consideration—

Mrs. CUBIN. The policy was based on 34 responses and I believe there are 154 or something like that more now.

Mr. BILIRAKIS. Right.

Mr. HASH. Briefly, it is my understanding, and I would like to make sure that I could correct my statements if I am speaking in error—it would be unintentional—but what I understand is that we did not have sufficient data or time at the time we got some information. The data situation may be changing.

It is important to recognize that in our evaluation of practice expense values for physician services, we are keeping open, during all 4 years of a transition to the new practice expense values, the opportunity to reweight or revise those practice expense values.

So even if for some reason it was not included in this year's practice expense rule that is coming out later, it would not be precluded from being considered subsequently because all of the practice expense values that are in place now are considered interim and subject to change based on data.

Mrs. CUBIN. Dr. Ganske and I were on opposite sides of that issue last year, I believe it was, because I do think we need an equalization of fees that are paid to cognitive as well as procedural medicine.

But my problem with this is that we settled on his way, on getting more information and new studies. So really I just think that the agency has to comply with what the Congress ordered and that is, in fact, what the Congress ordered—all the expenses to be considered.

Mr. BILIRAKIS. That all practice costs be considered, and that is the significant thing here. I would probably tend to side more with Ms. Cubin's view, but the point of the matter is that we do not want to sway from the intent of the Congress, which I think is clear that all practice costs be considered.

Mr. HASH. I understand, Mr. Chairman.

Mr. BILIRAKIS. All right.

Now the bell has gone off. We have a series of votes. There are four people over here who have not had an opportunity to talk with

Mr. Hash and I do not want to take that opportunity away from them. So I guess we had better just go ahead and break.

Mr. TOWNS. If I could just ask one quick question?

Mr. BILIRAKIS. Well, I want to get you back here.

Mr. TOWNS. I want to come back, especially after I read—

Mr. BILIRAKIS. Go ahead with your one question.

Mr. TOWNS. [continuing] that Mr. Hash was happy to be here.

Mr. BILIRAKIS. But I want to hear that you are happy to be here.

We are going to break for—we will let Mr. Towns ask his one question, if it is okay with Mr. Hash.

Mr. HASH. Yes.

Mr. BILIRAKIS. And then we are going to go ahead and break for a good half hour anyhow because we have a series of votes. I think it is only two, maybe more.

Mr. TOWNS. Thank you, Mr. Chairman. I will be brief.

Under the current projections, New York City Hospital stands to lose 40 percent of their revenue from outpatient reimbursement. We also have a major problem with reductions in indirect medical education.

Given the financial constraints that we are facing, wouldn't it make a lot of sense for HHS to fix the outpatient problem administratively and the Congress to address the cuts in medical education payments? Wouldn't that make sense?

Mr. HASH. We are working on that hospital outpatient rule and we obviously have not published our final rule and we expect to make a number of changes based on the kind of comments that we have been getting during the comment period.

Mr. TOWNS. Let me say that during the break I had an opportunity to do a lot of things with hospitals involved. I even visited folks that were ill in the hospital, had an opportunity to be administrative shadow for a day, had an opportunity to attend several luncheons. I even attended a board meeting and I had an opportunity to talk to staff who have worked at the hospital for 25 and 30 years. I attended a ceremony where people have been working for 30 years in the hospital.

And I must say to you that I am concerned in terms of the kind of service that is being rendered at some of these hospitals, the fact that the staff were complaining about excessive work and being stressed, and all these things affect patient care.

I think we need to be very, very careful as we look at this and I think that maybe we need to be more involved in terms of the Congress sitting down and talking with you but to be honest with you, as I listened to patients in the hospital talking about the lack of service and listening to staff talking about they cannot provide any more, and then I think I heard you say something about the staffing and in all these hospitals, the staffing has gone down, there is reduced staff in major kinds of ways, to the point where some people are saying that there is nothing else to cut, there is nothing else they can take away. And, at the same time, we are talking about making further cuts in some instances.

So I want to let you know I am very concerned about it and I think that, Mr. Chairman, maybe we need to, not only in this hearing but sit down and have some real dialog about this health care because this is a serious issue we are dealing with.

Mr. BILIRAKIS. I have already made the statement and Mr. Hash has agreed that we are going to sit down with him and his people. And I know that at least one of his staff people here has already approached the staff with the idea of sitting down with them and we are going to do that.

We are going to invite both sides of this entire subcommittee and I would hope that you would show up and make your points at that time so we can get something really——

Mr. TOWNS. I would be delighted to participate. I am concerned.

Mr. BILIRAKIS. And I have voiced the same concerns that you have, that I am sort of disappointed that HCFA has not seen fit to approach us and say hey, these are some of the things that need to be changed in the statute to allow us to do better.

Mr. HALL. Mr. Chairman, under your leadership and with the enormity of the problem that we have and because we are in a different atmosphere than we were when we started the balanced budget approach in the 1980's and finally concluded it in the 1990's, that we not adjourn when they set a date this year to adjourn, like October 15, that we not adjourn, that we stay here for another month and solve this problem.

We are losing people. Folks are going bankrupt. People are going without treatment. It is a disaster and there is an answer and the answer is money and we have more money now than we had when we wrote the Balanced Budget Amendments.

Mr. BILIRAKIS. October 29 was the target date which was set up earlier in the year. We have already been told that we will be fortunate to get out of here before Thanksgiving.

The fact of the matter is we are planning to sit down with Mr. Hash——

Mr. HALL. We really ought to stay and get our work done.

Mr. BILIRAKIS. If we stay, we may be able to get at them.

Michael, I cannot relieve you because apparently I do not want to keep anybody from inquiring.

Mr. HASH. I understand.

Mr. BILIRAKIS. So we will go in recess for a half hour.

[Brief recess.]

Mr. BILIRAKIS. This hearing is back in session and thank you, Michael, for being so patient with us.

The Chair recognizes Mr. Burr to inquire.

Mr. BURR. Mike, welcome, and my apologies for my absence. And if I cover anything that we have already been over, just let me know and I will read the testimony.

Let me ask you, of the options that exist relative to the therapy cap that have been battled around, is there any suggestion or recommendation that HCFA has for us relative to legislative remedies?

Mr. HASH. We are definitely looking at options with regard to this. We are going to meet. The chairman and I had a discussion earlier about meeting later this week to discuss specific kinds of proposals and options and I am actually not in a position today where I can lay all those options out for you, but we intend to do that with the committee and its staff. We want to explore that area in particular because, as I said earlier, we have reason to believe that in some settings, the therapy cap is really not adequate to

meet the needs of certain kinds of patients, particularly patients in nursing home settings, and we want to see what can be done about that.

Mr. BURR. You mentioned I think in your testimony or in some reference that you were examining information from Wall Street regarding trends in Medicare and I just wonder if you can tell us what type of information that is and what you are receiving and comment on investors as it relates to the attractiveness of this health care delivery system.

Mr. HASH. The information we have been reviewing, Mr. Burr, has not been so much about the opinions of people who are in the investment business as much as it has been looking at SEC filings in which corporations obviously have to disclose material financial issues to their stockholders and to the public, and we have been looking at that as some kind of indication about the financial health or viability—

Mr. BURR. When we see a 50 percent drop in the assets of long-term care facilities, should that be a sign that policymakers look at for health conditions?

Mr. HASH. It should be, but as I know you know, as we have looked at the nursing home industry that you are referring to, we have come to the judgment, as has, I think, the GAO and IG, as well, that many factors have gone into the changing asset values of those companies. Medicare policy certainly may be one aspect of it, but clearly there are other business decisions, or market conditions, which have put some of these firms in financial jeopardy, that are unrelated to the Medicare payment system.

Mr. BURR. But you would not object if the whole industry was affected from an asset value after BBA 1997? Granted there were some individual players that had business decisions that were evaluated differently but the industry was devalued in asset value based upon the changes.

Mr. HASH. I honestly am not sufficiently familiar from an industry-wide basis. We have been concentrating on the 10 largest national chain organizations to get a sense of, particularly those that are publicly traded, what has been happening in their filings. And, as some people have pointed out earlier, on Monday, Vencor Corporation filed for Chapter XI bankruptcy protection.

Mr. BURR. The financial health of that industry, you would agree, has an effect on any long-term expansion plans that they might have?

Mr. HASH. I am certain that it would, yes.

Mr. BURR. Let me ask you and I was told that you went over this ground but I would like to give you one more opportunity to answer it for me. I think HCFA has interpreted the outpatient statutory language such that hospital outpatient payments are \$900 million less per year.

Now HCFA received a letter from quite a few members of this institution. I was one of those. And simply how would HCFA respond to that?

Mr. HASH. What we have said, Mr. Burr, is that we recognize that this is a serious problem. It has been brought to our attention by all sorts of people. And we have asked our general counsel at

HHS to review the statutory language closely and carefully to see if we have any basis for coming to a different conclusion—

Mr. BURR. Was there something that was not clear in the letter from those Members of Congress that, in fact, the way HCFA interpreted was not the intent of Congress in the language?

Mr. HASH. I think where we are, Mr. Burr, is that we have done the best job we have to read the actual language of the statute and when we have done that, we believe that the interpretation that we have applied to it is the appropriate one.

We are still looking, however, to see if, in fact, there are alternative ways of evaluating the intent here. As I know you know—

Mr. BURR. Not to be adversarial but what is a better way to interpret the intent than to ask the people who wrote it, which is, I think, what the letter confirmed?

Mr. HASH. The letter does express that view and that is correct, Mr. Burr, but I think our judgment on this is that we are still trying to make sure that we are implementing the law as it was written. We have not come to a conclusion here in the end. That is what I said earlier. We are still reviewing this matter and we have not made a final judgment.

Mr. BURR. Well, my only hope is that that letter has clarified in the minds of those at HCFA what the congressional intent of that legislation spelled out.

Let me ask you very quickly on home health care, would HCFA recommend today that we delay the October 1, 2000 PPS plans and the 15 percent reduction?

Mr. HASH. We would not, Mr. Burr.

Mr. BURR. Will HCFA suggest or recommend any changes to the current reimbursement structure that we have for home health?

Mr. HASH. Well, we are on the verge of publishing a proposed rule for the home health prospective payment system and I think people will see in that proposed rule the kinds of approaches that we have taken, trying again to follow the BBA admonition.

Mr. BURR. But one could interpret that under the PPS it would meet the letter of the law, which is that there has to be at least a 15 percent reduction from where we started?

Mr. HASH. Yes, sir. I believe our view is that the statute is extraordinarily explicit with regard to that issue.

Mr. BURR. I realize my time has run out. I would remind the chairman and also for the purposes of HCFA that I remember sitting in the same room when the administration introduced this insane plan that had a 15 percent arbitrary cut at a predetermined date sometime in the future for home health. And when pressed, the then-administrator of HCFA said yes, it was a budget decision that stuck a number to meet a financial figure. And I said at that time I hope we are not crazy enough to adopt it, and I did.

I came to Congress for one reason—to have a balanced budget. In 1997 that one issue forced me to vote no on BBA 1997.

Today I feel good about that but the reality is I think it was still arbitrary at the time. It is wrong today and I am hopeful, Mr. Chairman, that this committee will look at it, along with HCFA, to determine whether there is a better way to do it so that it is fairly applied and so that that specific industry, which we looked at a number of years ago as a significant piece of the cost savings

picture for Medicare—if we can move patients out of hospitals faster because of care they can be given off-premise, that, in fact, we reach a more efficient and cost-effective system. And I think to some degree, they have now gotten hung up in everything else that is being squeezed.

I thank you, Mike.

Mr. BILIRAKIS. I thank the gentleman. I would just merely say that I think the BBA 1997 accomplished most of its objectives but, as I also said in my opening statement, there are a lot of unintended consequences, unforeseen problems. Bigness will do that and God knows we are talking about bigness here. It is up to us to try to correct those problems but first we have to admit that there are problems there.

Mr. BURR. Let me acknowledge that the attempt was a very good attempt. It is just I was torn on just how bad that one provision smelled. Thank you.

Mr. BILIRAKIS. Well, you were being ultra careful, I guess.

Mr. Deutsch to inquire.

Mr. DEUTSCH. Thank you, Mr. Chairman. I just mentioned to my staff that in the 12 steps, the first is an acknowledgement that there is a problem, so at least we are one step along the way.

Particularly I guess this is a timely question. Could you explain to us the changes in nursing homes who are forced to evacuate residents, as some have, because of the impending hurricane throughout almost 1,000 miles of the East Coast of the United States, who would pay for this transportation, how has it changed under BBA when the patients are transferred, and what risks do patients face in that?

It is my understanding that there is actually a BBA change regarding transportation factors in terms of nursing home residents, that it is a nonreimbursable expense at this point in time.

Mr. HASH. I must say I am not sure I understand fully your question, or maybe I am not fully familiar with the facts here, but I am not aware that if a nursing home has to be evacuated because of a natural disaster or other reason that puts individuals in jeopardy of their safety or their health, that the cost of transferring those patients would likely be borne through costs that the program, on a proportionate basis, would incur because not all of the individuals would be individuals who are being paid for under Medicare, for example.

Mr. DEUTSCH. Right. But my understanding is that that transportation, emergency transportation expense, there is no provision, and actually your staff is probably providing the answer at this point.

Mr. HASH. Well, it is an answer I had actually sort of thought of, which was that there was a change in the BBA in the nursing home PPS system. The change requires that for individuals who are in a nursing home for what is called a Medicare Part A stay, a skilled stay, that ambulance services that are for services that should otherwise be covered by the nursing home because the person is a resident there, would not be covered.

If there is an emergency however, like an individual has a heart attack or some emergency while they are in the nursing home in a Part A stay, the transportation to the emergency room and hos-

pital would be a covered service. It is just that routine transportation, for purposes of services that could otherwise be provided in the nursing home, is not covered but an emergency case would be covered.

Mr. DEUTSCH. So your explanation is that an evacuation in a pending hurricane would be covered?

Mr. HASH. I would like to discuss that with you further. I am not sufficiently familiar—

Mr. DEUTSCH. The good news is that it does not happen very often.

Mr. HASH. Right.

Mr. DEUTSCH. But my understanding is that it is unreimbursable.

Mr. HASH. I would be happy—

Mr. DEUTSCH. I am sure there is an answer but what nursing homes have told me is that—

Mr. HASH. That is not reimbursable?

Mr. DEUTSCH. That is correct, yes. And again obviously it does not make any sense. So it is just one of these unintended consequences.

Let me follow up, and I know you have had some questions on this but not in the kind of detail hopefully we can get into.

On the \$1,500 cap, which I have heard your response to Mr. Burr, as well as earlier, and I think all of us acknowledge that there is a problem with that, how does HCFA reconcile the cap on the covered therapies with the skilled nursing facility OBRA requirements to require all care and services to enable the residents to attain, and both of us are aware of this, the highest practical level of physical and psychological and sociopsychological well-being?

Do the nursing home surveys take this into consideration that services are not covered, for instance, when issuing citations? And specifically, has HCFA at this point stopped enforcement on these issues, with the acknowledgement of the problems related to the caps?

Mr. HASH. Well, this is an important and complicated question, Mr. Deutsch. The first thing is that many nursing home residents are covered under Medicaid and therefore that program in most States, and I think this is the case in Florida, that program actually covers therapy services that are provided to nursing home residents under Medicaid.

So with respect to medically necessary therapy services for an individual who has a nursing home stay that is being covered under Medicaid, it would be covered under that benefit.

With respect to an individual who is in a Part A Medicare stay, that individual actually, the prospective payment rate includes an allowance for therapy services that is not related to the \$1,500 cap. So there is no cap, dollar cap on therapy services to residents who are in a Part A stay.

Mr. DEUTSCH. Right. But percentagewise, and you have probably and your staff I am sure has it far better than I do; my guess is we are talking in terms of Medicaid-eligible in a nursing home, we are talking less than 50 percent almost for sure. So we still have that gap issue.

Mr. HASH. But the other 50 percent, I believe, is private pay.

Mr. DEUTSCH. Right, but private pay in terms of the level of private pay out of pocket when you are hitting that \$1,500 becomes totally cost-prohibitive in terms of families, I mean in terms of middle class families. Private pay does not mean that people have millions of dollars to spend in terms of ancillary care.

I guess I am just trying to—and unfortunately, that 5 minutes goes pretty fast—I am really trying to get a sense, and your staff has actually met with me on this issue and talked about trying to get a fix on what really is going on in facilities and I have met and I am talking with nursing home operators about what is happening in the real world and talked we therapists, as well.

And I do not think there is a question that people are falling through the cracks at this point in time. What is your best feel for how many people are falling through the cracks? I mean the typical person is the stroke victim who goes through their Part A but still is in the nursing home and needs clearly beyond the \$1,500 cap of therapy. What a physician would normally recommend—that, I think, is just one category of patient that easily fits into that category.

And I guess the reason why I ask the question the way I did, first of all, I had a concern that I have expressed to your staff that I think we really are in a conflict for the Medicare statute itself in terms of medically necessary services. But I think we are also in a conflict in terms of the OBRA requirements of the skilled nursing facilities in terms of treatment of patients.

Mr. BILIRAKIS. A brief response to that, please, so we can let you go.

Mr. HASH. I understand the problem and I think you are correct in saying there are individuals whose needs are not being met by this benefit because of the limit. That is why I said in my statement that this is one of the areas that we wanted to explore, to make sure that our beneficiaries were getting access to therapy services that they need. And we do need to fix that if we can and I think that is a part of our commitment to working with the Congress to address the therapy cap issue.

Mr. BILIRAKIS. Okay. Now the gentleman's time, of course, has expired.

There will be written questions submitted to you and because we trust and hope that with all of us working together, this is on a fast path, we would hope that those responses will be sooner rather than later.

Mr. HASH. I understand, Mr. Chairman.

Mr. BILIRAKIS. Additionally, I understand your staff is meeting with our staffs probably later on this week for sure, so hopefully next week we can sit down around a table and Mr. Deutsch should hear this—I am not sure whether you were here when we talked about this earlier but we are going to meet with Mr. Hash around the table here and try to work things out.

Now prior to that, I wonder; you have admitted, I think, and I understand that others have been talking to the White House and they have admitted that there are areas where you can have administrative fixes.

Mr. HASH. Yes, sir. And we have tried to take those actions.

Mr. BILIRAKIS. Could you maybe share those with us at the gathering that we have hopefully next week?

Mr. HASH. Yes, sir.

Mr. BILIRAKIS. If you can, that way maybe we can put those aside and work on the areas that possibly we need to be further involved in.

Mr. HASH. Yes, sir.

Mr. BILIRAKIS. If there is nothing more, we very much appreciate your taking the time. I know you had something else to do and we kept you considerably longer than we had hoped to.

Mr. HASH. I appreciate it. I am glad to have the opportunity and I think this was a very useful and valuable exchange. It helps to obviously form the basis for our working together to address this in the weeks ahead.

Mr. BILIRAKIS. Thank you. Thank you very much.

The next panel consists of Dr. Murray Ross, executive director of the Medicare Payment Advisory Counsel that we fondly refer to as MedPAC; Mr. Daniel L. Crippen, director of CBO; and Mr. William J. Scanlon, director of Health Financing and Public Health at GAO.

Gentlemen, first I want to thank you for your patience and your consideration. I think all of you have gone through this before so you know what that can be like. I also apologize because we lost our panel, too, and that always is what happens. That is why I keep telling the staff that we should not have these large witness panels because invariably that is what happens. By the time the third panel gets up here, God only knows how many people will be here.

So you have 5 minutes. Your written statement, of course as you know, is already a part of the record. We would hope that you would supplement and complement that. We will kick it off with Dr. Ross. Please proceed, sir.

STATEMENTS OF MURRAY N. ROSS, EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION; WILLIAM J. SCANLON, DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH, GENERAL ACCOUNTING OFFICE; AND DAN L. CRIPPEN, DIRECTOR, CONGRESSIONAL BUDGET OFFICE

Mr. Ross. Thank you. Good afternoon Mr. Chairman and Ms. DeGette.

I am pleased to be here representing MedPAC to discuss what we know and do not know about the implications of the BBA for beneficiaries and providers in Medicare's traditional fee-for-service program. I will also discuss very briefly some of our recommendations that we think would improve Medicare's payments and preserve access to care for beneficiaries.

The BBA had an ambitious objective and to expect legislation so sweeping to achieve this objective flawlessly is, of course, unrealistic. But providers' complaints notwithstanding, we have no evidence that wholesale changes are either necessary or desirable.

Now providers' concerns are clearly relevant to any assessment of the BBA but, at the same time, we must remember that Medicare's objective is to provide access to high quality care for beneficiaries. Assessing the implications of the BBA should therefore

focus on whether access to or quality of care has been impaired and, if so, what can be done about it?

Measuring access is difficult and attributing changes to access to specific changes in policy even more so. Therefore, policymakers often look at determinants of access, such as the financial measures that may affect the supply of providers and at their willingness to serve Medicare beneficiaries.

During the past year, various indicators have been cited to demonstrate the impact that the BBA has had on providers. The hospital industry, for example, has issued several reports analyzing hospital revenues and margins. A second example is the closures of home health agencies since the IPS, the interim payment system, was put in place, and I think Bill Scanlon will talk to you about those.

In the case of hospitals, MedPAC staff has analyzed the reports and we believe they somewhat overstate the impact of the BBA on margins, in some cases by overestimating what happened to costs in 1998. They do, however, correctly present its overall direction. Medicare payments are no longer rising more rapidly than costs.

But what this means for Medicare policy is not yet clear. First, the pressures that hospitals are facing reflect not only Medicare's payment policies but also continued pressures on revenues from other payers.

Second, because hospitals will respond to financial pressures by attempting to slow cost growth, projected margins serve only as a gauge of that pressure, not as a prediction of what will occur.

Industry and policy analysts have expressed concerns that the new prospective payment system for nursing facilities and the IPS for home health agencies will make these providers unwilling to serve Medicare beneficiaries with extensive needs. Concerns have also been raised about the new system for determining physician fees. Three studies, one by the HHS inspector general, that looked at nursing facility access and two by MedPAC, indicate that these concerns have not yet generated widespread problems.

To assess concerns about access under the interim payment system, MedPAC surveyed about 1,000 home health agencies earlier this year. Virtually all of the agencies we surveyed accept new patients but the number accepting all new Medicare patients is now about 75 percent; that is down from about 85 percent before the IPS. About 40 percent of the agencies reported that they no longer accept certain patients that they accepted before IPS and 30 percent reported discharging patients because of the IPS. Agencies identified long-term or chronic care patients as the ones they no longer admitted or discharged.

Now while these are consistent with the claim that the IPS has hampered access, these findings also do not tell the entire story. First, the changes in payment policy that were put in place were accompanied simultaneously by policies at HCFA to reduce fraud and abuse. HCFA, as you know, also adopted the sequential billing procedure for processing home health claims.

And finally, assessing the impact on beneficiaries is confounded because we do not know whether the changes in the use of home health services are appropriate.

Our second survey was intended to assess the effects of changes in how physicians are paid. The BBA introduced a single conversion factor that reduced payment rates for surgical services and generally increased them for other services.

We surveyed 1,300 physicians on their willingness to serve Medicare beneficiaries and the results were reassuring. Among physicians accepting all or some new patients, 95 percent accepted new Medicare fee-for-service patients both in 1997 before the changes were put in place and in early 1999.

The vast number of changes to Medicare's payments make it essential to continue monitoring access. And MedPAC, along with GAO and HCFA, will do so. On the payment side, MedPAC's March and June reports note where we believe policy changes are not yet warranted and recommend specific targeted policies that could alleviate some of the concerns regarding access to care in the future. Let me highlight some of the latter.

There has been a lot of discussion regarding the prospective payment system for outpatient hospital services this morning and MedPAC too is concerned with this system. We feel it is too aggregated, making it likely to overpay for some services in a group and underpay for others. This could lead to future access problems for beneficiaries needing services whose payments fall short of costs. MedPAC recommends that the PPS be based on the cost of individual services.

And, as you heard, implementing the PPS will reduce payments for virtually all hospitals and significantly for specific types of hospitals. MedPAC recommends monitoring access closely to ensure that access to hospital outpatient services is not compromised. We also think that consideration should be given to phasing in the new payment system to help us detect any problems before they become severe.

The OIG report provides some comfort that anecdotal reports of access problems for beneficiaries needing skilled nursing care do not indicate a widespread problem today, but MedPAC is concerned that the mismatch between payments and costs for some high acuity patients could cause problems in the future and we recommend refining the system to improve its ability to predict the use of non-therapy services and supplies.

In the short run, a PPS for home health care that accounts for differences among beneficiaries will remedy some of the concerns about the IPS, but the timetable is very tight. So we recommended in June that Congress consider a progress for agencies to exclude a small share of their payments from the per-beneficiary limits.

In the longer run, ensuring that Medicare beneficiaries have access to appropriate home health care requires clarifying the benefit and to that end, we recommend that the secretary speed development of regulations that would base eligibility and coverage for those services of clinical factors and recommend legislation to the Congress to enact them.

Let me make one final recommendation concerning the physician payments. The problems with the sustainable growth rate system that updates payments for physicians have received less publicity than changes in facility payments. But as we heard earlier today, uncorrected projection errors and possible wide swings in payment

updates raise questions about access problems in the future to physician services. MedPAC recommends that the Congress require the secretary to correct estimates used in the SGR calculations and enact legislation to modulate swings in those updates.

That concludes my statement and I will be happy to answer any questions you have.

[The prepared statement of Murray N. Ross follows:]

PREPARED STATEMENT OF MURRAY ROSS, EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION

Good morning Chairman Bilirakis, Congressman Brown, members of the Committee. I am Murray Ross, executive director of the Medicare Payment Advisory Commission (MedPAC), and I am pleased to be here to discuss what we know and do not know about the implications of the Balanced Budget Act (BBA) of 1997 for beneficiaries and providers in Medicare's traditional fee-for-service program. I will also discuss recommendations that MedPAC made in its two reports to the Congress earlier this year and other options you may wish to consider.

The changes enacted in the BBA and implemented by the Health Care Financing Administration (HCFA) reduced Medicare payment rates relative to what they would have been otherwise and, not surprisingly, have generated concerns among providers about their effects. Providers' concerns frequently have been heightened by their perception that the effects have been more harsh than the Congress intended, or that the effects, while intended, have nonetheless imposed burdens on providers, and that there are specific problems with how HCFA has implemented the law. My testimony today focuses on five types of services—inpatient hospital, outpatient hospital, skilled nursing, home health, and physician—that have been the subject of much discussion this year.

Summary

A greater than expected slowdown in Medicare spending began in fiscal year (FY) 1998 and has continued this year. Medicare spending rose only 1.5 percent last year, compared with a projection of 5.7 percent by the Congressional Budget Office when BBA was enacted. Through the first 10 months of FY 1999, outlays are running about 1 percent below the FY 1998 rate for the same period.

Unfortunately, we cannot draw definitive conclusions about what the slowdown in spending means for providers and beneficiaries. Almost two years have gone by since the first BBA policies were put in place, but systematic data for this period are still extremely limited. Moreover, we cannot easily isolate the effects of the BBA from other changes. Hospitals, for example, have argued that the changes in Medicare payments stemming from the BBA are reducing their margins and impinging on their ability to provide quality care. But the most recent complete information we have for the Medicare program is from FY 1997, the year before the BBA took effect. And the limited data we have now do not let us separate out the effects of Medicare's policies from other changes. For home health services, we have seen lower than expected outlays, closures of home health agencies, and declines in the use of services. But our interpretation of these findings is clouded by other policy changes, notably efforts by HCFA and the Department of Justice to cut down fraud and abuse in the home care industry, and by the lack of clear eligibility and coverage guidelines for home health care.

The BBA had an ambitious objective for Medicare's fee-for-service program: modernizing payment systems and slowing the growth in spending while preserving Medicare beneficiaries' access to high-quality health care. To expect legislation as sweeping as the BBA to achieve this objective flawlessly is unrealistic. In a number of instances, targeted changes in statute or in regulation could improve Medicare's payments and access to care for beneficiaries. But providers' complaints notwithstanding, we have no evidence that wholesale changes in the BBA are either necessary or desirable.

How did the BBA change payments to providers?

The BBA enacted the most far-reaching changes to the Medicare program since its inception. The law reduced payment updates or otherwise slowed the growth in payments to virtually all fee-for-service providers. It established, or directed to be established, new prospective payment systems for services provided by hospital outpatient departments, skilled nursing facilities, and home health agencies. Finally, the law revised the mechanism for updating fees for physician services.

Inpatient hospital services

The BBA changed payments for inpatient hospital services in a number of ways. For hospitals under Medicare's prospective payment system (PPS), the law provided for no update to operating payments in FY 1998 and limited updates in FY 1999 through FY 2002. It required phased reductions in the per-case adjustments for the indirect costs of medical education (IME) and, temporarily, for hospitals serving a disproportionate share (DSH) of low-income patients. And it instituted a new transfer policy for 10 high-volume diagnosis related groups (DRGs), reducing the payment rates when hospitals discharge patients in these DRGs to post-acute care facilities following unusually short stays.

By themselves, lower updates would have slowed the growth in payment rates to hospitals for inpatient services but would not have reduced them. In FY 1998, however, the combined effect of the freeze on payment rates, smaller IME and DSH payment adjustments, and a small decline in the case mix index reduced payment rates in absolute terms. In FY 1999 and later years, however, payment rates should begin to increase again, albeit at a slower rate than would have occurred in the absence of the BBA.

Outpatient hospital services

In addition to changes in payments for inpatient services, the BBA also enacted major changes in Medicare's payments for services provided in hospital outpatient departments. It eliminated the so-called formula-driven overpayment under which Medicare's payments did not correctly account for beneficiaries' cost-sharing and extended the reduction in payments for services paid on a cost-related basis. The law also directed the Secretary to establish a prospective payment system for services that have been paid at least partially on the basis of incurred costs.

Hospitals have not yet felt the full impact of the BBA provisions affecting outpatient services. MedPAC estimates that elimination of the formula-driven overpayment, which took effect in 1998, reduced payments by about 8 percent. However, the PPS that was to have gone into effect in January 1999 will not be put in place before next summer. HCFA originally estimated that the PPS would reduce payment rates by 3.8 percent, on average, but has since revised its estimate of the reduction to 5.7 percent. These estimates likely overstate the ultimate reduction, however, as hospitals will have an incentive to code outpatient services more accurately than they do now.

Services in skilled nursing facilities

The BBA enacted a prospective payment system for services provided in skilled nursing facilities (SNFs). These services had previously been paid on the basis of costs, subject to limits on routine services. Under the new system, payments are intended to cover the routine, ancillary, and capital costs incurred in treating a SNF patient, including most items and services for which payment was previously made under Part B of Medicare. Patients in SNFs are classified under the Resource Utilization Group system, version III (RUG-III), which groups patients by their clinical characteristics for determining per diem payments.

The new payment system slows spending growth for SNF services by moving these facilities from cost-based reimbursement to federal rates that are based on average allowable per diem costs in FY 1995, trended forward using the increase in the SNF market basket index less 1 percentage point. Because nursing home spending—particularly for ancillary services—grew rapidly between FY 1995 and FY 1997, using FY 1995 as the base for payment purposes reduced payments for many nursing homes. The PPS is being phased in over a four-year period that began in 1998. Payments in FY 1999 are based on a 50/50 blend of federal rates and facility-specific rates and will be based entirely on the federal rates beginning in FY 2001.

Home health services

Before the BBA, home health agencies were paid on the basis of costs, subject to limits based on costs per visit. The BBA directed the Secretary to implement a prospective payment system effective October 1999—since delayed by the Congress to October 2000—and established an interim payment system (IPS) intended to control the growth in spending until the PPS was in place. The IPS reduced the limits based on costs per visit and introduced agency-specific limits on average costs per beneficiary based on a blend of agency-specific costs and average per-patient costs for agencies in the same region. Home health agencies are now paid the lower of their actual costs, the aggregate per-beneficiary limit, and the aggregate per-visit limit. Agencies' per-beneficiary limits are based on their average costs per beneficiary in FY 1994, trended forward using the home health market basket index. As with nursing homes, home health spending grew rapidly in the mid-1990s. For this

reason, using FY 1994 as a base for payment led to substantial payment cuts for some home health agencies.

Physicians' services

The BBA replaced the volume performance standard system that had been used to update physicians' fees with a new sustainable growth rate (SGR) system. It also introduced a single conversion factor for all physician services that reduced payments for some services while increasing them for others. Finally, the BBA established requirements for payments to physicians for their practice costs.

Unlike some of the other provisions of the BBA, changes to Medicare's payments to physicians occurred almost immediately. Starting on January 1, 1998, the single conversion factor was implemented along with the first step toward revising practice cost payments. The effects of these changes were largest for some surgical procedures, such as cataract surgery and some orthopedic procedures, where payment rates fell by 13 percent or more. Payment rates for other services went up, however. Payments for office visits and some diagnostic services increased by at least 7 percent.

What has been the impact of these payment changes?

Providers' concerns are clearly relevant to any assessment of the BBA. But at the same time, we must remember that the primary objective of the Medicare program is to maintain access to high-quality care for beneficiaries. Assessing the implications of the BBA should therefore focus on whether access to or quality of care has been hampered and, if so, what can be done about it.

In evaluating the potential impact of the BBA on access and quality, two issues seem especially important. One is how payment policies for different services may interact to affect providers' ability and incentives to furnish care. Many hospitals, for example, furnish most types of services, including skilled nursing services and home health care. Consequently, they must face the combined effects of policy changes that have altered payments for virtually every service they provide.

A second critical issue is whether the new payment systems adequately reflect predictable differences in patient care costs. Industry and other analysts have raised this issue with regard to the new payment system being developed for outpatient hospital services, the PPS being phased in for skilled nursing facilities, and the IPS for home health agencies. Where predictable differences in costs are not taken into account, financial incentives are created for providers to deny access to care or undertreat identifiable groups of patients.

Sorting out the effects of multiple changes in payment policies and the introduction of new payment systems on beneficiaries' ability to obtain the medical services they need is challenging in two important respects. First, many BBA changes have not yet been fully phased in, and data to evaluate the impact of recent changes are in many cases not yet available. Second, measuring access to care is difficult. Because directly measuring appropriate beneficiary use of services is hard to do with existing data, policymakers often look at determinants of access, such as provider availability and willingness to serve Medicare beneficiaries, as well as the nature and extent of other barriers to access that beneficiaries face. Interpreting the findings of these analyses can be difficult, however, because we cannot isolate the effects of changes in Medicare policy from the effects of other changes in health care financing or delivery arrangements.

Financial impacts

During the past year, various indicators have been cited as measuring the financial impact that the BBA is having on providers. The hospital industry, for example, has issued several reports analyzing the impact of the BBA on hospital revenues and margins. A second example is the closures of home health agencies since the IPS was put in place. Industry and other observers have cited declines in the number of agencies as putting beneficiaries' access to home health care services at risk.

Hospitals. The reports issued by the hospital industry contain new projections, but they do not present new data. In response to congressional requests, MedPAC staff has analyzed these projections and found that all of them portray a more adverse impact of the BBA than we believe to be the case. Some present a particularly inaccurate picture of the impact in FY 1998 by assuming a rate of increase in costs that substantially exceeds what we already know to have occurred. Data from the American Hospital Association's National Hospital Panel Survey suggest that when complete Medicare cost report data become available later this year, we will again see a decline in Medicare cost per discharge for FY 1998, the fifth year in succession.

Although we believe that industry reports somewhat overstate the impact of the BBA on hospital margins, they do correctly present its overall direction. As it was intended to do, the law has reversed a six-year trend of Medicare payments rising

more rapidly than the costs of treating Medicare beneficiaries. Still, two reasons make it difficult to interpret what changes in total margins mean for Medicare policy. First, the financial pressure that hospitals are currently experiencing reflects both changes in Medicare's payment policies and continued strong downward pressure on revenues from private managed care plans and other payers. In FY 1997, private payers' payments dropped by 4 percentage points relative to the cost of treating their patients, while Medicare payments rose relative to costs. Data for FY 1998 are not yet available, but we have every reason to believe that the downward pressure from private payers continued as Medicare reduced its payments. Second, because hospitals can be expected to continue responding to financial pressures by slowing cost growth—the overall increase in costs per case for all patients has been below 2.5 percent for five straight years—projected margins serve only as a gauge of financial pressure, not as a prediction of what will occur. MedPAC has seen no convincing evidence that the changes to date have affected either quality or access in the inpatient sector, but we will continue to monitor developments.

Home health agencies. To examine whether the closures of home health agencies may have affected beneficiaries' access to services, the General Accounting Office (GAO) analyzed the distribution of closures across urban and rural counties. The agency also interviewed stakeholders' representatives of state agencies, beneficiary advocates, hospital discharge planners, and managers of home health agencies—in 34 primarily rural counties that had experienced significant agency closures or declines in the use of services. GAO concluded that the closures have had little impact on Medicare beneficiaries to date. However, the agency noted that beneficiaries who are more costly than average may face difficulty in obtaining home health care in the future as agencies change their behavior in response to the IPS.

The GAO study found that while about 14 percent of agencies had closed between October 1, 1997, and January 1, 1999, more home health agencies were in existence at the beginning of FY 1999 than at the beginning of FY 1996. The study found that most of the closures occurred in urban counties and that about 40 percent of the closures occurred in three states—Louisiana, Oklahoma, and Texas—that had seen a large expansion in the number of agencies and that had utilization rates well above the national average.

Stakeholders interviewed by the GAO reported few access problems currently. State survey agency representatives, for example, indicated that adequate capacity continued to exist despite the closures and reported that they had received few complaints about access to Medicare home health care. Discharge planners and home health agency managers reported that beneficiaries living in counties that had lost agencies still had adequate access through agencies located in adjacent counties.

Willingness to serve beneficiaries

Industry and policy analysts have expressed concerns about the case-mix adjuster used in the new PPS for skilled nursing facilities and the lack of case-mix adjustment in the IPS for home health agencies. Concerns have also been raised about the new system for determining physicians' fees.

Skilled nursing facilities. In the case of SNFs, concerns have centered around the payment weights used in conjunction with the RUG-III system. Although SNF patients can vary significantly in their use of ancillary services and supplies such as drugs and biologicals, payments for patients in different RUG-III categories are based on estimates of the time providers' staff spent furnishing nursing and therapy services. SNFs may be unwilling to serve patients in some high-acuity RUG-III groups for whom the costs of services may exceed the payment rates.

The Office of the Inspector General (OIG) of the Department of Health and Human Services has undertaken a study to assess these concerns. The OIG surveyed a random sample of 200 hospital discharge planners responsible for arranging nursing home care for patients being discharged from hospitals.

The OIG report concluded that while serious problems in placing Medicare beneficiaries in nursing homes are not apparent, SNFs are changing their admitting practices in response to the new payment system. Two-thirds of discharge planners responding to the survey reported no difficulty in placing Medicare patients. At the same time, almost half of the discharge planners surveyed reported that nursing homes have begun requesting more detailed clinical information about patients and more often assessing patients directly before making admissions decisions.

The survey found that some patients have become harder to place, including those who need extensive services, such as intravenous feedings or medications, tracheostomy care, or ventilator and respirator care. These findings are consistent with concerns that payment weights under the PPS do not account adequately for certain medically complex patients.

Home health agencies. The IPS for home health agencies has been criticized because the aggregate per-beneficiary limit is based on historical patterns of use and does not account for changes in agencies' patient mix. Industry and beneficiary representatives have asserted that this limitation has made home health agencies unwilling to accept patients who are likely to need extensive services.

To assess these concerns, MedPAC contracted with Abt Associates, Inc., to survey about 1,000 home health agencies in early 1999 on their experience under the IPS. We also convened a panel of experts familiar with beneficiaries' problems accessing home health services.

The results of our survey of home health agencies are consistent with the preliminary information we have on utilization. The agencies we surveyed generally reported that their Medicare caseloads have fallen and that the number of visits per user they provide has decreased. Almost half reported that they had changed the mix of services they provide, with fewer aide visits being the most common response. While virtually all of the agencies we surveyed reported that they are accepting new patients, the share accepting all new Medicare patients was 75 percent, compared with 85 percent before the IPS was implemented. About 40 percent of agencies reported a change in admissions practices—refusing to admit patients that they would have accepted before the IPS—and 30 percent reported discharging patients because of the IPS. Agencies most frequently identified long-term or chronic care patients as those they no longer admitted or have discharged.

These findings are consistent with the claim that the IPS has hampered access, but they do not tell the whole story because the change in payment policy occurred at the same time HCFA was implementing other policies intended to reduce fraud and abuse, including stepping up oversight of home health care providers and imposing a four-month moratorium on the certification of new agencies in early 1998. The agency also adopted a new procedure for processing claims for home health care services. Assessing the effect on beneficiaries of changes in home health agencies' willingness to serve them is further confounded because we cannot determine whether the changes in use of home health services observed during the past two years are appropriate. Medicare's standards for eligibility for and coverage of home health services are too loosely defined for us to do so.

Physician services. Three aspects of the new mechanism for setting physicians' fees have raised questions regarding their impact on access. First, the introduction of a single conversion factor reduced payment rates for surgical services, while payment rates for primary care and other nonsurgical services generally increased. Second, the Secretary's lack of authority to correct for projection errors and the potential for oscillations in fee updates under the SGR system have raised questions about whether updates are appropriate. Because the SGR is cumulative, uncorrected projection errors affect all subsequent updates. This happened in 1999, when an unexpected slowdown in Medicare+Choice enrollment growth led to a smaller than projected decline in Part B fee-for-service enrollment. Third, the SGR system as currently designed has the potential for oscillation in fee updates because of problems with the data and methods used to calculate the updates. These problems are likely to lead to extreme positive and negative updates.

To assess the effects of the payment changes introduced in 1998, MedPAC contracted with Project HOPE to survey 1,300 physicians on their willingness to serve Medicare beneficiaries. The survey data were reassuring. Among physicians accepting all or some new patients, over 95 percent were accepting new Medicare fee-for-service patients both in 1997, before the new payment policy changes were implemented, and in early 1999. The survey also found that only about 10 percent of physicians reported changing the priority given to Medicare beneficiaries seeking an appointment. Of those, the percentage giving Medicare patients a higher priority was almost the same as the percentage giving Medicare patients a lower priority.

Where do we go from here?

Although there is no systematic evidence to date that beneficiaries' access to care has been impaired, the vast number of changes to Medicare payment policy introduced by the BBA make it more important than ever to monitor access. In our March and June reports to the Congress, MedPAC noted where we believe policy changes are not yet warranted and recommended specific targeted policies that could help to alleviate some of the concerns that have been raised regarding access to care in the future..

Hospital inpatient services

In our March report, MedPAC concluded that the operating update for FY 2000 enacted in BBA—1.8 percentage points less than the increase in HCFA's operating market basket index or 1.1 percent—will provide reasonable rates. In formulating

our recommendation, MedPAC took into account part, but not all, of the cumulative reduction in costs per case that has occurred. We noted that hospitals have responded to an increasingly competitive market by improving their productivity and by shifting services to other sites of care. At the same time, we recognized factors pointing to the need for caution in specifying future updates, including emerging evidence that the decade-long trend in rising case mix complexity, which automatically increases PPS payments, may be subsiding. We also questioned whether the unusually low rate of hospital cost growth observed in recent years can be sustained without adverse effects on quality of care.

Hospital outpatient services

MedPAC has concerns about the PPS proposed by HCFA for hospital outpatient services. In basing payments on groups of services, instead of individual services, the system is likely to overpay for some services and underpay for others. This could lead to access problems in the future for beneficiaries needing services whose payments fall short of costs. In our March report, MedPAC recommended that the PPS be based on the costs of individual services. Since that recommendation was made, HCFA has been collecting comments on its PPS proposal, with the formal comment period ending July 30, 1999. HCFA will review the comments with the assistance of a private contractor, 3M Health Information Systems. HCFA then plans to issue a final regulation at least 90 days before the PPS is implemented.

Implementing the outpatient PPS will reduce payments for virtually all hospitals but could have much larger effects on specific types of hospitals. For example, based on HCFA's original estimates—which do not take into account improvements in coding that will lead to smaller reductions—small rural hospitals would see a 17 percent decline in payment rates, and cancer hospitals would see a drop of more than 30 percent. Given these changes, MedPAC recommended that the Secretary closely monitor the use of hospital outpatient services to ensure that beneficiaries' access to appropriate care is not compromised. Consideration should also be given to phasing in the new payment system to help us detect any problems before they become severe.

Skilled nursing facilities

The OIG report on the willingness of skilled nursing facilities to continue accepting Medicare beneficiaries provides some comfort that early anecdotal reports of access problems do not indicate a widespread problem. Nonetheless, MedPAC remains concerned about the mismatch between payments and costs for patients who require relatively high levels of nontherapy ancillary services and supplies could hamper access in the future. In our March report, we recommended that the Secretary continue to refine the classification system to improve its ability to predict the use of nontherapy services and supplies. An improved classification system would match payments more closely to beneficiaries' needs for services and help to avoid access problems among medically complex patients. HCFA has indicated that it is researching the adequacy of payments under the PPS and will implement refinements next year if that research indicates changes are warranted.

Home health services

Implementing a PPS for home health care services that accounts for differences among beneficiaries will help to ensure access for those who require extensive care. MedPAC is concerned, however, that the timetable for implementing the PPS is very tight. Accordingly, we recommended in our June report that the Congress explore the feasibility of establishing a process for agencies to exclude a small share of their patients—say 2 percent—from the aggregate per beneficiary limits. Under our recommendation, Medicare would reimburse care for excluded patients based on the lesser of actual costs or the aggregate per-visit limits. MedPAC believes that such a policy should be implemented in a budget-neutral manner.

In the longer run, ensuring that Medicare beneficiaries have access to appropriate home health care services will require clarifying the benefit. To that end, MedPAC recommended that the Secretary speed the development of regulations that would outline home health care coverage and eligibility criteria based on the clinical characteristics of beneficiaries and that she recommend to the Congress the legislation needed to implement those regulations.

Physicians' services

In part because of their technical nature, problems with the sustainable growth rate system that determines updates to payments for physicians' services have received less publicity than concerns about facility payments. But because uncorrected projection errors and wide swings in payment updates could raise access problems in the future, MedPAC recommends that the Congress require the Secretary to cor-

rect estimates used in SGR system calculations every year and that legislation be enacted to modulate swings in updates.

Mr. BILIRAKIS. Thank you very much.
Dr. Scanlon?

STATEMENT OF WILLIAM J. SCANLON

Mr. SCANLON. Thank you very much, Mr. Chairman. I am very pleased to be here today as you discuss the issues that have arisen regarding the changes made to the fee-for-service Medicare program in the Balanced Budget Act.

I will focus my remarks today on the changes affecting several of the postacute care providers, namely home health agencies, skilled nursing facilities, and outpatient therapists. We have undertaken several studies to review BBA impacts for these services at the request of this committee and others.

Concerns, as you know, have been raised in the industries involved about the BBA's impacts on beneficiary access and on the financial viability of providers. The issue is how valid are these concerns.

The BBA made necessary and fundamental changes, in our view, to Medicare's payment methods to slow spending growth while protecting appropriate beneficiary care. Prior to the BBA, spending for these services, especially home health and SNF care, was growing very rapidly. No analyses supported why the growth should be so high and there were significant concerns that overutilization, inefficient delivery and fraud and abuse played a role.

While refinements may be required to make the BBA payment systems more effective, their design intentionally makes inefficient providers change their practice patterns to remain in the Medicare business.

The impact of payment reforms on home health agencies has been very noticeable because Medicare is such a major share of agencies' business and the interim payment system was implemented without a transition.

Our findings are very similar to those reported by Dr. Ross for MedPAC. We reported in May that the number of home health agencies certified for Medicare had declined 14 percent since the implementation of the interim payment system and that utilization had returned to 1994 levels. There has been an increase in the number of closures since then, though utilization measures have not been assembled.

Despite this, because of the number of agencies had virtually doubled between 1990 and 1997, beneficiaries, when we reported, were still being served by over 9,000 agencies, approximately the same number that were available in 1996.

Furthermore, the drop in utilization does not appear to be related to agency closures. Rather, it is consistent with the incentives that the interim payment system imposes to control the volume of services provided to beneficiaries and to narrow the widely divergent and unexplained variation in use.

While access generally has not seemingly been impaired, there are indications, as Dr. Ross indicated, that some beneficiaries who are likely to be more costly than average may have more difficulty obtaining home health services. The revenue caps imposed by the

interim payment system are not adjusted to reflect variations in patient needs, a problem that we need ameliorated and will be ameliorated with the implementation of the prospective payment system.

Turning to skilled nursing facilities, there are several factors that might suggest that the PPS's impact on the viability of SNFs would be less severe than is being claimed by providers.

First, Medicare is a small portion of most skilled nursing facilities' business. Furthermore, only a quarter of Medicare's current reimbursement for most facilities is based on the prospective rate. The remainder reflects the facility's own historical spending, spending that may be inflated due to the provision of excessive ancillary services in the past.

Nevertheless, we are here today, 2 days after one of the largest nursing home chains filed for Chapter XI bankruptcy protection. We have been reviewing the difficulties of Vencor and other nursing home chains for the Senate Finance and Aging Committees. It would appear to us that Vencor and other companies' difficulties likely relate to much more than simply the prospective payment system for Medicare.

Overall, the skilled nursing facility prospective rates may have actually been set too high on average and thus overcompensate rather than undercompensate providers. Nevertheless, it seems that certain modifications to prospective payment may be appropriate.

As Dr. Ross also indicated, there is evidence the payments are not being appropriately targeted to patients who require costly care—in Mr. Hash's terms, the high acuity patient. The potential access problems that result for such patients if Medicare underpays for their care will likely lead to beneficiaries remaining in acute care hospitals longer rather than foregoing care, an important point to remember.

HCFA is aware of the situation, as you have heard, and is working to address the problem.

Finally, let me comment on where the BBA imposed a fee schedule on all outpatient therapy services and replaced the \$900 cap on therapy provided by independent therapists with the \$1,500 cap on outpatient physical and speech therapy and a separate \$1,500 cap on occupational therapy.

In our view, these caps represent a legitimate attempt to control service use to avoid utilization increases and avoid eliminating the savings to be generated from all the changes in provider fees that have been mandated by the BBA. The per-beneficiary caps, furthermore, are unlikely to curtail services for the vast majority of outpatient therapy users, principally because the principal provider of outpatient therapy, hospital outpatient departments, are exempted from the cap.

However, even though the caps may be important to generate some control over use, the caps do not take account the differences in patient needs, and restricting coverage for patients who have a genuine need for services is very problematic.

Therefore, HCFA's efforts to try and design a needs-based payment system taking into account clinical factors, as mandated by the BBA, is critical.

In conclusion, I would note that the BBA made necessary and fundamental changes to Medicare's payment methods for many providers in order to slow spending growth while preserving appropriate beneficiary care. Further refinements, as you have noted, are required to make these systems more effective. However, these systems' intent is to require inefficient providers to adjust their practice patterns to remain viable.

It is important that all the changes that we consider and any change that is enacted be based upon the most complete and solid information that is available. To prematurely change this would undermine the intent and goal of BBA, which are essential to the long-term sustainability of the Medicare program. Thank you very much, Mr. Chairman. I would be happy to answer questions you may have.

[The prepared statement of William J. Scanlon follows:]

PREPARED STATEMENT OF WILLIAM J. SCANLON, DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, GAO

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today as you discuss the effects of the Balanced Budget Act of 1997 (BBA) on the Medicare fee-for-service program. BBA set into motion significant program changes to both modernize Medicare and rein in spending. The act's constraints on providers' fees, increases in beneficiary payments, and structural reforms together were projected to lower Medicare spending by \$386 billion over the next 10 years. Because some BBA provisions have only recently been implemented or have not yet been phased in, the act's full effects on providers, beneficiaries, and taxpayers will remain unknown for some time.

BBA was enacted in response to continuing rapid growth in Medicare spending that was neither sustainable nor readily linked to demonstrated changes in beneficiary needs. The act's payment reforms represented bold steps to control Medicare spending by changing the financial incentives inherent in payment methods that, prior to BBA, did not reward providers for delivering care efficiently. To date, the Congress has remained steadfast in the face of intense pressure to roll back certain BBA payment reforms while waiting for evidence that demonstrates the need for modifications. Calls for BBA changes come at a time when federal budget surpluses and lower-than-expected growth in Medicare outlays could make it easier to accommodate higher Medicare payments. However, as the Comptroller General cautioned in July, the surpluses are merely projections and could fall short of expectations and the imperative remains to find the reforms that will make Medicare sustainable and affordable for the longer term.¹

My comments today focus on the reforms governing payments to three providers of post-acute care services—home health agencies (HHA), skilled nursing facilities (SNF), and providers of outpatient rehabilitation therapy. Among BBA's changes affecting various providers, these reforms are farthest along in their implementation. Furthermore, it is important to consider the payment policies for these providers together because changes to payments for one of them could affect the costs and utilization of another.

In brief, providers of such post-acute care services as home health care, SNF care, and rehabilitation therapy may have to change their service delivery practices as a result of BBA payment reforms, which seek to make Medicare a more efficient and prudent purchaser. Calls to amend or repeal these BBA changes may be premature until information is available to identify and distinguish between desirable and undesirable consequences. At the same time, imperfections in the design of BBA-mandated payment systems require attention. The design details of these systems are key to ensuring that payments are not only adequate in the aggregate but are also fairly targeted to protect individual beneficiaries and providers.

With regard to home health care, the effect of the interim payment system on HHAs has raised concerns. Our May 1999 analysis indicated, however, that the reductions in the number of HHAs and changes in home health utilization were consistent with the incentives of the interim payment system to control the rapid and

¹ *Medicare Reform: Observations on the President's July 1999 Proposal* (GAO/T-AIMD/HEHS-99-236, July 22, 1999).

unexplained growth that had preceded the BBA.² Furthermore, we found little evidence that appropriate access to Medicare's home health benefit has been impaired. The interim payment system, however, is not an appropriate payment method for the long term because it does not adjust payments for differences in beneficiary needs. Therefore, it is important to implement the BBA-mandated prospective payment system (PPS), scheduled for October 1, 2000. In ongoing work, we are examining the formidable challenges of designing a PPS with the appropriate unit of payment, level of payment, case-mix adjustment method, and risk-sharing mechanism. Our work indicates that the PPS will likely require further adjustments after it is implemented as more information on home health costs, utilization, and users becomes available.

The SNF PPS was implemented beginning July 1998 with a 3-year transition to fully prospective rates; thus, time for providers to adjust to the payment change has been built into the implementation schedule. Our ongoing work examining whether the PPS is causing financial problems for some SNFs suggests that factors in addition to the PPS have contributed to fiscal difficulties. Nevertheless, certain modifications to the PPS may be appropriate, as there is evidence that payments are not being adequately targeted to patients who require costly care. The potential access problems that may result if Medicare underpays for high-cost cases could lead to beneficiaries' staying in acute care hospitals longer, rather than foregoing care altogether. HCFA is aware of this potential targeting problem and is working to develop a solution.

Beginning this year, BBA imposed an annual \$1,500 per-beneficiary cap on payments for outpatient physical and speech therapy combined and a separate \$1,500 cap on outpatient occupational therapy, while exempting hospital outpatient departments from these caps. The act also replaced reasonable cost reimbursement for these services with payment under a fee schedule. The caps reflect a legitimate need to constrain service use. While not calibrated to accommodate variation in beneficiary needs, the per-beneficiary caps are unlikely to curtail access to services for the vast majority of outpatient therapy users. Only a small share of beneficiaries receiving therapy services use outpatient therapy extensively. Further, most of those users with greater needs will likely have access to hospital outpatient departments, which are not subject to the \$1,500 caps. In addition, owing to HCFA's partial approach to enforcing the caps while year 2000 adjustments are made to Medicare's automated systems, noninstitutionalized beneficiaries can avoid having the caps curtail service coverage by switching providers. However, the caps may restrict coverage for some nursing home residents, resulting in their having to pay out-of-pocket or seek payment from other sources, such as Medicaid, for therapy services. Studies are under way or planned to better measure the effect of the caps and how they might be adjusted. BBA also required HCFA to recommend a need-based payment system, which could help better target payments toward beneficiaries who genuinely require more services than allowed under the current dollar limits.

BACKGROUND

The Medicare program consists of two parts: "hospital insurance," or part A, which covers inpatient hospital, skilled nursing facility, hospice, and certain home health care services, and "supplementary medical insurance," or part B, which covers physician and outpatient hospital services, outpatient rehabilitation services, home health services under certain conditions, diagnostic tests, and ambulance and other medical services and supplies.

Prior to BBA payment reforms, Medicare experienced rapid growth in the services beneficiaries receive after a hospitalization (also called post-acute-care services), primarily due to increased utilization. During much of the 1990s, home health care was one of Medicare's fastest growing benefits; between 1990 and 1997, Medicare spending for home health care rose at an annual rate of 25.2 percent. Several factors accounted for this spending growth, most notably the relaxation of coverage guidelines. In response to a 1988 court case, a change in the coverage guidelines essentially transformed the benefit from one that focused on patients needing short-term care after hospitalization to one that serves chronic, long-term-care patients as well.³ The loosening of coverage and eligibility criteria contributed to an increase in the number of beneficiaries receiving services and the volume of services they received. Associated with this rise in utilization was an almost doubling in the number of Medicare-certified HHAs to 10,524 by 1997.

² *Medicare Home Health Agencies: Closures Continue, With Little Evidence Beneficiary Access Is Impaired* (GAO/HEHS-99-120, May 26, 1999).

³ *Dhaka v. Bowen*, 691 F. Supp. 1487 (D.D.C. 1988).

Also contributing to the historical rise in home health care spending were a payment system that provided few incentives to control how many visits beneficiaries received and lax Medicare oversight of claims. As we noted in a previous report, even when controlling for diagnoses, substantial geographic variation existed in the provision of home health care, with little evidence that the differences were warranted by patient care needs.⁴ Additional evidence indicates that at least some of the high use and the large variation in practice represented inappropriate billings and unnecessary care.⁵ Medicare oversight declined at the same time that spending mounted, contributing to the likelihood that inappropriate claims would be paid. To begin to control spending, BBA implemented an interim payment system for HHAs beginning October 1, 1997. A PPS is scheduled to be implemented for all HHAs on October 1, 2000.⁶

As required by BBA, on July 1, 1998, SNFs began a 3-year transition to a PPS, under which providers are paid a prospective rate for each day of care. Previously, SNFs were paid the reasonable costs they incurred in providing Medicare-covered services. Although there were limits on the payments for the routine portion of care (that is, general nursing, room and board, and administrative overhead), payments for ancillary services, such as rehabilitative therapy, were virtually unlimited. Because higher ancillary service costs triggered higher payments, facilities had no incentive to provide these services efficiently or only when necessary. Thus, between 1992 and 1996, daily ancillary costs grew 18.5 percent a year, compared to 6.4 percent for routine service costs. Moreover, new providers were exempt from the caps on routine care payments for up to their first 4 years of operation, which encouraged greater participation in Medicare.

Rehabilitation therapy comprises a substantial portion of the post-acute-care services provided by SNFs and other providers, such as rehabilitation therapy agencies and comprehensive outpatient rehabilitation facilities. Under BBA, the prices of therapy services provided in outpatient settings are controlled by a fee schedule.⁷ Generally, when prices are fixed, providers can compensate by increasing the volume of services delivered. To control volume, coverage for outpatient therapy is now limited to \$1,500 per beneficiary for physical and speech therapy, with a separate \$1,500 per-beneficiary limit for occupational therapy. Hospital outpatient departments are exempt from these coverage limits.

LITTLE EVIDENCE TO DATE OF IMPAIRED ACCESS TO HOME HEALTH SERVICES, BUT FUTURE PAYMENT SYSTEM WILL REQUIRE REFINEMENTS

By October 2000, HCFA is required to establish a new PPS for home health care—with a fixed, predetermined payment per unit of service, adjusted for patient characteristics. Until that time, HHAs are paid under the BBA-mandated interim payment system. Although concerns have been raised about the effect of the interim system, our May 1999 analysis showed little evidence that appropriate access to Medicare's home health benefit has been impaired under this payment method. Nevertheless, a home health PPS is a more appropriate payment tool because it can align payments with patient needs. Designing an adequate home health care PPS, however, poses substantial challenges.

The pre-BBA payment system had controls for payments per visit but left volume unchecked. Since enactment of the BBA, home health agencies have been paid under the interim payment system, which attempts to control the costs and amount of services provided to each beneficiary. Indeed, our work indicates that overall home health utilization in the first 3 months of 1998 had declined since 1996, but utilization was about the same for a comparable period in 1994. Moreover, the sizeable variation in utilization between counties with high and low use has narrowed. Although these changes occurred at the time that about 14 percent of HHAs closed

⁴*Medicare: Home Health Utilization Expands While Program Controls Deteriorate* (GAO/HEHS-96-16, Mar. 27, 1996).

⁵*Medicare: Improper Activities by Mid-Delta Home Health* (GAO/T-OSI-98-6) and Office of the Inspector General, Department of Health and Human Services, *Variation Among Home Health Agencies in Medicare Payment for Home Health Services* (July 1995). Our 1997 analysis of a small sample of high-dollar claims found that over 40 percent of these claims should not have been paid by the program. See *Medicare: Need to Hold Home Health Agencies More Accountable for Inappropriate Billings* (GAO/HEHS-97-108, June 13, 1997).

⁶BBA required the HHA PPS to be in place in fiscal year 2000. Subsequent legislation delayed the implementation by 1 year and required that there be no transition to the PPS.

⁷Payments for inpatient rehabilitation therapy services, such as those provided by SNFs, HHAs, and rehabilitation facilities, are not subject to the fee schedule and are paid under other rules. In addition, outpatient therapy provided by critical access hospitals is not subject to the fee schedule.

their doors to Medicare business, we found little evidence that beneficiary access to services was inappropriately curtailed.

The PPS should be a substantial improvement over the interim payment system because payments will reflect current beneficiaries and their needs rather than historical spending patterns. However, our ongoing work on this subject shows that a number of design issues remain and the payment system will likely require continued adjustments even after implementation of the PPS next year. HCFA will pay HHAs a per-episode rate for up to the first 60 days of services to a patient. Such per-episode payments are designed to balance competing goals of controlling service provision while giving HHAs flexibility to vary the intensity or mix of services delivered during the episode. Evidence indicates that HHAs do lower their costs in response to prospective payments for an episode of care. Whether they will inappropriately cut visits, which could reduce the quality of care and cause Medicare to pay for services that were not delivered, remains to be seen. Under this prospective payment approach, HHAs also have incentives to increase the number of episodes of care provided, which could escalate, rather than constrain, Medicare spending. HCFA will need to adequately monitor service provision to ensure that beneficiaries receive the care they need and the number of episodes are not inappropriately increased.

The design of the case-mix adjustment mechanism is critical to adequately pay for patients with high services need, yet not overpay for others with lower requirements. Designing this mechanism requires detailed information about services and beneficiary characteristics, and such information is currently available only for a sample of users. Furthermore, the wide geographic and agency-level variation in service use indicates that standards of care are not well-defined, nor are the criteria for who should use the benefit. As a result, the factors that will be used under PPS for grouping patients with similar resource needs may not adequately distinguish among types of home health patients, and the PPS payment adjuster that will be associated with each patient group may not reflect appropriate cost differences. Systematic errors could result in overpayments for some beneficiaries and underpayments for others. Underpayments could lead to impaired access.

Large variations in historic spending patterns mean that a PPS, which will be based on average payment amounts, may cause payment levels to rise for certain HHAs and fall for others. Although the PPS may incorporate an outlier policy—that is, extra payments for extremely costly cases—additional mechanisms to moderate payment changes may be appropriate. For example, an “inlier” policy to reduce the payment for a patient who receives few services may be warranted, particularly given the fact that multiple episode payments may be made for a single beneficiary. Policies addressing both extremes of service use could protect the access of beneficiaries with high needs and protect Medicare from overpaying for low-cost cases. A risk-sharing method, to account for cost differences across agencies, could provide further protection against underpayments or overpayments. Given the heterogeneous use of this benefit and the unresolved PPS design issues, moderating payments through risk-sharing might be warranted, even if such a mechanism would reduce HHAs’ incentives to curtail providing unneeded care.

AGGREGATE PAYMENTS TO SNFS ARE ADEQUATE, BUT REFINEMENTS NEEDED TO HELP MATCH PAYMENTS TO PATIENTS’ SERVICE NEEDS

Despite industry charges to the contrary, SNF payment rates under BBA are likely to provide sufficient, or even generous, compensation for providers. Nevertheless, the distribution of these payments may be out of balance, because the current case-mix adjustment method may not adequately ensure that providers serving high-cost beneficiaries are paid enough and that those serving low-cost beneficiaries are not paid too much.

Under the new PPS, SNFs receive a payment for each day of covered care provided to a Medicare-eligible beneficiary. By establishing fixed payments and including all services provided to beneficiaries under the per diem amount, the PPS attempts to provide incentives for SNFs to deliver care more efficiently. Under the PPS, SNFs that previously boosted their Medicare ancillary payments—either through higher use rates or higher costs—will need to modify their practices more than others. Scaling back the use of these services, however, may not necessarily affect the quality of care. There is little evidence to indicate that the rapid growth in Medicare spending was due to a commensurate increase in Medicare beneficiaries’ need for services.

Recent industry reports have questioned the ability of some organizations that operate SNF chains to adapt to the new PPS. Indeed, pending bankruptcies have been claimed to be the results of the Medicare payment changes. Our ongoing work sug-

gests that PPS has been only one of many factors contributing to the poor financial performance of these corporations. For one thing, Medicare patients constitute a relatively small share of the business of most SNFs and for these corporations, SNFs are only a portion of their overall revenues. Moreover, the PPS rates are being phased in, to allow time for facilities to adapt to the new payment system, and most of the payments are still tied to each facility's historical costs. The reality is that some corporations invested heavily in the nursing home and ancillary service businesses in the years immediately before the enactment of the PPS, both expanding their acquisitions and upgrading facilities to provide higher-intensity services. Under tighter payment constraints, these debt-laden enterprises are particularly challenged. Thus, while SNFs will have to adapt to the PPS constraints, the performance of some large post-acute providers is a reflection of many Medicare payment policy changes and strategic decisions made during a period when Medicare was exercising too little control over its payments. We are gathering additional information and will report soon on the effect of the PPS on SNF solvency and beneficiary access to care.

We believe that overall payments to SNFs are adequate. In fact, we and the Department of Health and Human Services Inspector General (HHS IG) are concerned that the PPS rates Medicare pays may be too generous. Most of the data used to establish these rates—from 1995 cost reports—have not been audited and are likely to include excessive ancillary costs due to the previous system's incentives and the lack of appropriate program oversight.⁸

We are concerned, however, that payments for individual beneficiaries could be inappropriately high or low because of certain PPS design problems. The first of these problems involves the patient classification system. The classification system was based on a small sample of patients and, because of the age of the data, may not reflect current treatment patterns. As a result, it may aggregate patients with widely differing needs into too few payment groups that do not distinguish adequately among patients' resource needs. In addition, the cost variation for non-therapy ancillary services may not have been adequately accounted for in the payment rates, which may inappropriately compress the range in payments. Accordingly, access problems or inadequate care could result for some high-cost beneficiaries. Hospitals have reported an increase in placement problems due to the reluctance of some facilities to admit certain beneficiaries with high expected treatment costs, which will increase hospital lengths of stay for these patients. HCFA is aware of the limitations of the case-mix adjustment method and is working to refine this system to more accurately reflect patient differences.

Another design problem is that the current case-mix adjustment method preserves the opportunity for SNFs to increase their compensation by supplying unnecessary services. A SNF can benefit by manipulating the services provided to beneficiaries, rather than increasing efficiency. For example, by providing certain patients an extra minute of therapy over a defined threshold, a facility could substantially increase its Medicare payments without a commensurate increase in its costs.

ADVERSE EFFECT OF OUTPATIENT THERAPY CAPS DOUBTFUL, BUT NEED-ADJUSTED PAYMENT LIMITS WOULD BE BETTER

Questions have been raised about a BBA coverage restriction for a third group of post-acute-care services—outpatient rehabilitation therapy. Together with a fee schedule that replaces reasonable cost reimbursement for these services, BBA imposed an annual \$1,500 per-beneficiary cap on payments for outpatient physical and speech therapy combined and a separate \$1,500 per-beneficiary cap on outpatient occupational therapy.⁹ Services provided by hospital outpatient departments are exempt from the per-beneficiary caps.

Rehabilitation therapy providers have raised concerns that the \$1,500 limits will arbitrarily curtail necessary treatments for Medicare beneficiaries, particularly victims of stroke, hip injuries, or multiple medical incidents within a single year. These concerns have led to several legislative proposals to include various exceptions to the caps or eliminate them altogether.

⁸ The HHS IG recently reported on the inappropriateness of the base year costs. See *Physical and Occupational Therapy in Nursing Homes: Cost of Improper Billings to Medicare* (HHS IG, OEI-09-97-00122, Aug. 1999).

⁹ Physical therapy includes treatments—such as whirlpool baths, ultrasound, and therapeutic exercises—to relieve pain, improve mobility, maintain cardiopulmonary functioning, and limit the disability from an injury or disease. Speech therapy includes the diagnosis and treatment of speech, language, and swallowing disorders. Occupational therapy helps patients learn the skills necessary to perform daily tasks, diminish or correct pathology, and promote health.

Our ongoing work on this topic for Members of this Subcommittee suggests that eliminating the caps without substituting other controls could undermine BBA's comprehensive strategy for restricting payments for outpatient therapy services. Controlling the price for each unit of service—as is done with the new requirement that that outpatient therapy providers bill Medicare according to the physician fee schedule—may not necessarily control Medicare expenditures if utilization rises. This is particularly likely, given the price and utilization controls imposed through PPS on other providers of rehabilitation therapy. Thus, the per-beneficiary caps serve to limit the volume of services provided.

For the vast majority of beneficiaries, the coverage caps are unlikely to curtail access to needed services. An analysis by the Medicare Payment Advisory Commission shows that, in 1996, most users (86 percent) did not exceed \$1,500 in payments for physical and speech therapy or for occupational therapy.¹⁰ Moreover, if the fee schedule constrains payments as expected, the proportion of beneficiaries that are unaffected by the caps could be even higher in 1999, because beneficiaries could receive more services before reaching the per-beneficiary caps than under the former cost-based system.

Even for beneficiaries exceeding \$1,500 in payments under the fee schedule, mitigating factors exist. First, under the BBA exemption, Medicare beneficiaries have no limits on coverage for rehabilitation therapy provided by hospital outpatient departments, which are widely available nationwide. In addition, the caps will initially not be applied as specified in BBA. Implementing the caps involves many programming changes to Medicare's automated information systems that HCFA is unable to undertake concurrent with its year 2000 preparation efforts. As a result, HCFA's claims processing contractors will be unable to track therapy payments on a per-beneficiary basis. Instead, effective January 1, 1999, HCFA employed a transitional approach to implementing the caps. Under this approach, each provider of therapy services is responsible for tracking its billings for each Medicare patient and stopping them at the \$1,500 threshold. The consequence of this partial implementation is that noninstitutionalized beneficiaries may switch to a new provider when they have reached the \$1,500 limit under the current provider.

The effect of the per-beneficiary caps on nursing home residents is less clear. The ability of beneficiaries to switch outpatient providers under HCFA's partial implementation approach is, practically speaking, not available to nursing facility residents. Under new billing requirements, the nursing facility in which the beneficiary resides is required to bill for outpatient therapy provided to the resident, regardless of the entity that actually delivered the service. Therefore, unlike their noninstitutionalized counterparts, nursing facility residents cannot switch providers to restart the \$1,500 coverage allowance. Under these circumstances, some nursing home residents—like those needing extensive rehabilitation therapy resulting from such conditions as stroke or hip fractures—could be vulnerable to out-of-pocket costs for therapy.

Even the risk for these more vulnerable beneficiaries may be moderated, however, because nursing home residents seeking therapy for such conditions would likely receive a complement of rehabilitation services as a SNF inpatient—before the outpatient therapy coverage limit begins to apply. That is, individuals suffering a stroke or undergoing hip replacement would likely spend at least 3 days in an acute care hospital, which, combined with the need for daily skilled nursing care or therapy, would make them eligible for a Medicare-covered SNF stay of up to 100 days, during which they would likely receive therapy services. After their Medicare coverage ends, a nursing facility resident can continue to receive outpatient therapy services under Medicare part B, subject to the coverage limits. BBA mandates that HCFA develop a classification system based on diagnosis to determine differences in patients' therapy needs and propose possible alternatives to the caps in a report due January 1, 2001. This report will be significant in that a need-based system could help ensure adequate coverage for those beneficiaries requiring an extraordinary level of services and prevent overprovision to those requiring only limited amounts.

CONCLUSION

In conclusion, the BBA payment reforms affecting providers of home health care, SNF care, and outpatient rehabilitation therapy are all intended to make these providers more efficient. As the reforms begin to have their intended effects, pressure

¹⁰A July 1998 report sponsored by the National Association for the Support of Long-Term Care and NovaCare, a rehabilitation services company, projects that 87 percent of beneficiaries will not exceed the per-beneficiary cap.

is building to return to more generous payment policies. Evidence to date shows that BBA is moving Medicare in the right direction but that adjustments will be needed along the way. These adjustments should be based on thorough, quantitative assessments so that misdiagnosed problems do not lead to misguided solutions. With the health care of seniors and the tax dollars of all Americans at stake, policy-makers must, in the face of pressure for increased payment rates, preserve new payment policies that exact efficiencies but make adaptations when substantiated evidence supports the need to do so.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you or other Members of the Subcommittee might have.

GAO CONTACTS AND ACKNOWLEDGMENTS

For future contacts regarding this testimony, please call Laura A. Dummit at (202) 512-7114. Individuals who made key contributions to this statement include Carol L. Carter, Assistant Director; Hannah F. Fein; James E. Mathews; and Deborah Spielberg.

Mr. BILIRAKIS. Mr. Crippen?

STATEMENT OF DAN L. CRIPPEN

Mr. CRIPPEN. Thank you, Mr. Chairman. Having listened to the opening statements by many of your colleagues, as well as the intense interest of the audience behind us, I have a feeling that this table is sitting at the eye of another hurricane.

Mr. BILIRAKIS. As is this table.

Mr. CRIPPEN. I do not know how far out the clouds reach.

I am pleased to represent the Congressional Budget Office here today, Mr. Chairman. We were here at the beginning, so it is only right that we return to the scene of the crime.

My colleagues on the panel today are in a better position to comment on the actual outcomes in the sense of what is happening to health care delivery than we are. We do mostly the input side of this business. But we do have some observations to make, and my written statement generally reinforces what my colleagues here have said, so I will try not to be overly redundant in capturing some of it.

I hope to make three points, Mr. Chairman. First, the greater-than-expected slowdown in the growth of Medicare spending stems largely from successful efforts to combat fraud and abuse and from delays in payments to health care providers. Second, with one exception, we believe that our estimates of the effects of the Medicare provisions of the Balanced Budget Act are still within reasonable ranges. CBO did not anticipate how home health agencies would implement the interim payment system for home health services, however, and may therefore have underestimated the savings of the provisions that apply to home health.

Third, the factors that are holding down the growth of Medicare spending, finally, Mr. Chairman, will play themselves out in the near future, and more rapid growth will then resume. This is temporary.

Just a quick context of where we are. Between 1980 and 1997, Medicare spending increased at an average rate of 11 percent a year and expanded from 5 percent of the budget to 12 percent. Total outlays for Medicare rose by only 1.5 percent last year, however, and we may actually have the first absolute decline in spending this year.

Part of that slowdown was anticipated. The Balanced Budget Act lowered the projected growth in Medicare spending by an estimated

4 percentage points in 1998. But the actual rate of spending growth is considerably slower than the BBA provisions alone were expected to produce. Other factors appear to have contributed to the sudden flattening of Medicare expenditures, including greater compliance with Medicare payment rules and a longer time for processing claims.

Widely publicized efforts to clamp down on fraud and abuse in the program have resulted in greater compliance by providers. Although the total reduction in spending growth attributable to the improved compliance cannot be quantified completely, CBO estimates that one response alone to recent enforcement efforts—less aggressive billing by hospitals—lowered growth in Medicare spending by 0.75 percentage points in 1998 alone. So just under one full percentage point by the coding in the hospitals.

The assignment of patients with respiratory infections to diagnosis-related groups provides one example of the change in billing practices. Patients with respiratory infections generally are assigned to one of two DRGs: respiratory infections, for which the Medicare payment averaged \$7,400 in 1998; or simple pneumonia, for which payments averaged \$4,900. From 1997 to 1998, the number of cases in the higher-paying DRG—respiratory infections—fell by 43,000 cases, while the number of cases assigned to the lower-paying DRG—simple pneumonia—increased by 42,000. That single change in coding reduced Medicare program spending by about \$100 million in 1998 alone.

In addition to these behavioral changes, Mr. Chairman, the average time for processing Medicare claims rose dramatically in 1998. Expanded compliance activities, combined with major efforts to prepare computer systems for the year 2000 contributed to longer payment lags, which can have a substantial effect on Medicare outlays. For example, an increase of 1 week in the average time for processing claims reduces Medicare outlays for the fiscal year by almost 2 percent. That reduction obviously is only temporary because the delay merely moves outlays into the next fiscal year.

Our observations, Mr. Chairman, on the specific services—that is, postacute care, physicians' services and in-hospital care—are very close or the same as my colleagues. I would just say, as Mr. Scanlon did, to remind us all that when you changed the payment rules for postacute care in particular, skilled nursing facilities and home health services, those two elements of Medicare were growing at an annual rate of 38 percent and 25 percent, respectively.

Economists have a kit bag of trite phrases that they like to haul out but that are probably not very useful. One is "This can't go on forever." Clearly those kinds of increases of 40 percent and 30 percent in these two programs could not have gone on and this gives you some of the reason why the impacts are apparently as severe as they are.

Let me skip to a final observation, Mr. Chairman, and we can move to your questions. Although Medicare spending has slowed dramatically in 1998 and 1999, CBO expects it to resume growth at an average rate of 7 to 8 percent in the decade after 2000. In particular, spending for home health services is likely to rebound after 2000, when the prospective payment system replaces the interim payment system.

Medicare spending is likely to grow even faster after 2010 with the influx of the baby-boom generation into that program. That growth is due both to the unprecedented increase in program enrollment and continuing increases in spending per enrollee. Assuming no change in policy, as we discussed this morning, the trustees' report projects that Medicare spending will grow from 2.5 percent of gross domestic product to about 5 percent of GDP in 2030. Such an expansion in program spending poses an unprecedented challenge to policymakers and to the country.

Thank you, Mr. Chairman.

[The prepared statement of Dan L. Crippen follows:]

PREPARED STATEMENT OF DAN L. CRIPPEN, DIRECTOR, CONGRESSIONAL BUDGET OFFICE

Mr. Chairman and Members of the Committee, I am pleased to represent the Congressional Budget Office (CBO) at this hearing on the fee-for-service portion of the Medicare program. After many years of rapid increases, the growth of Medicare spending has slowed sharply in the past two years. My statement discusses the reasons for that slowdown and presents CBO's assessment of future trends. I will make three main points:

- The greater-than-expected slowdown in the growth of Medicare spending stems mainly from successful efforts to combat fraud and from delays in payments to health care providers.
- With one exception, CBO's estimates of the effects of the Medicare provisions of the Balanced Budget Act (BBA) of 1997 still appear reasonable. CBO did not anticipate how home health agencies would implement the interim payment system for home health services, however, and may therefore have underestimated its savings.
- The factors that are holding down the growth of Medicare spending will play themselves out in the near future, and more rapid growth will then resume.

TRENDS IN MEDICARE SPENDING

Between 1980 and 1997, Medicare spending increased at an average rate of 11 percent a year and expanded from 5 percent to 12 percent of the federal budget. Total outlays for Medicare rose by only 1.5 percent in 1998, however, and are expected to decline in 1999. Part of that slowdown was anticipated; the Balanced Budget Act lowered the projected growth of Medicare spending by an estimated 4 percentage points in 1998. The BBA reduced payment rates for many services and restrained the update factors for payments through 2002. Both fee-for-service providers and Medicare+Choice plans are experiencing lower increases in payments as a result.

But the actual rate of spending growth is considerably slower than the BBA provisions alone were expected to produce. Other factors appear to have contributed to the sudden flattening of Medicare expenditures, including greater compliance with Medicare payment rules and a longer time for processing claims.

Widely publicized efforts to clamp down on fraud and abuse in the program have resulted in greater compliance by providers with Medicare's payment rules. Those efforts include more rigorous screening of claims by Medicare contractors and tougher enforcement of Medicare laws by the Departments of Justice and Health and Human Services. Through investigations and lawsuits, those agencies have pursued a wide range of providers—including hospitals, teaching physicians, home health agencies, clinical laboratories, and providers of durable medical equipment—as well as Medicare contractors themselves. Although the total reduction in spending growth attributable to the improved compliance cannot be quantified, CBO estimates that one response alone to recent enforcement efforts—less aggressive billing by hospitals—lowered growth in Medicare spending by 0.75 percentage points in 1998.

The assignment of patients with respiratory infections to diagnosis-related groups (DRGs) provides one example of the change in billing patterns. Patients with respiratory infections generally are assigned to one of two DRGs: respiratory infections, for which the Medicare payment averaged \$7,400 in 1998; or simple pneumonia, for which payments averaged \$4,900. From 1997 to 1998, the number of cases in the higher-paying DRG (respiratory infections) fell by 43,000, while the number of cases assigned to the lower-paying DRG (simple pneumonia) increased by 42,000. That

change in coding reduced Medicare program spending by about \$100 million in 1998.

In addition, the average time for processing Medicare claims rose dramatically in 1998. Expanded compliance activities, combined with major efforts to prepare computer systems for 2000, contributed to longer payment lags, which can have a substantial effect on Medicare outlays. An increase of one week, for example, in the average time for processing claims reduces Medicare outlays for the fiscal year by about 2 percent. But that reduction is only temporary because the delay merely moves outlays into the next fiscal year.

CBO expects that improved compliance with payment rules and longer claims-processing times will have little or no effect on the rate of growth of Medicare spending in the longer run. Our projections assume that payment lags will begin to return to more typical levels late in 2000, with a catch-up in spending and a resumption of normal spending growth in 2001 and 2002. Most of the projected increase over the next few years reflects rising expenditures per enrollee. The leading edge of the postwar baby boom will not reach age 65 until after 2010.

Medicare outlays to date for fiscal year 1999 are actually lower than they were for the same period last year (see Table 1). CBO's current projections of aggregate Medicare spending, as updated in July 1999, reflect those lower-than-expected outlays and smaller-than-expected adjustments of payment rates for inflation in 2000. CBO assumes that lower payments for home health services and a drop in the case-mix index (a measure of the relative costliness of the cases treated in hospitals paid under the prospective payment system) explain most of the shortfall in Medicare spending so far this year. However, CBO does not yet have the data needed to update the detailed projections of spending by category of service that were prepared in March 1999. Therefore, my discussion of service-specific spending will reflect the March projections.

TABLE 1. Medicare Outlays Based on the July 1999 Baseline
(By selected fiscal year)

	1990	1998	1999	2004	2009
In Billions of Dollars					
Gross Mandatory Outlays					
Benefits	107	210	208	297	440
Mandatory administration and grants ¹	2	1	1	1	1
Total	107	211	210	298	442
Premiums	-12	-21	-22	-34	-53
Mandatory Outlays Net of Premiums	96	190	188	264	389
Discretionary Outlays for Administration	2	3	3	4	4
All Medicare Outlays Net of Premiums	98	193	191	267	393
Average Annual Growth Rate from Previous Year Shown (Percent)					
Gross Mandatory Outlays		8.8	-0.7	7.3	8.2
Premiums		7.5	3.9	9.6	9.3
Mandatory Outlays Net of Premiums		9.0	-1.2	7.0	8.0
Discretionary Outlays for Administration		1.5	-2.6	6.8	4.0
All Medicare Outlays Net of Premiums		8.8	-1.2	7.0	8.0

SOURCE: Congressional Budget Office.

NOTE: Numbers may not add up to totals because of rounding.

¹ Mandatory outlays for administration support peer review organizations, certain activities against fraud and abuse, and grants to states for premium assistance.

² Less than \$500 million

Projections of Spending and Enrollment in the Medicare Fee-for-Service Program

CBO projects that spending in Medicare's fee-for-service program will increase from \$178 billion in 1998 to \$302 billion in 2009 (see Table 2). That growth will occur despite shrinkage in fee-for-service enrollment, which will decline by 1.5 million over the next decade, and cuts in the growth of payment rates for many services.

Spending growth for different services will vary considerably over the same period. The extent of the recent slowdown in spending has also varied by type of service, although spending for all services has been affected by the 1.9 percent drop in

fee-for-service enrollment that occurred in 1998 and the further 0.8 percent decline expected in 1999.

Postacute Care Services. Payments for skilled nursing facility (SNF) and home health services grew very rapidly during the decade preceding passage of the Balanced Budget Act. Between 1988 and 1997, spending for skilled nursing services grew at an average annual rate of 38 percent, while growth in spending for home health services averaged 25 percent a year. That spending growth slowed significantly in 1998.

TABLE 2. Outlays for Medicare Benefits, by Sector, Based on the March 1999 Baseline
(By fiscal year)

Sector	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
In Billions of Dollars												
Medicare+Choice ¹	32	37	41	49	48	60	70	88	88	108	124	141
Fee-for-Service												
Skilled nursing facilities	13	13	13	14	14	15	16	17	18	19	21	22
Home health	15	15	17	16	17	18	20	21	23	24	26	28
Hospice	2	2	2	2	3	3	3	3	3	3	4	4
Hospital inpatient ²	87	86	91	95	99	104	108	112	117	123	129	135
Physicians' services	32	32	33	34	35	36	37	38	39	40	41	43
Outpatient facilities	17	16	17	18	20	21	23	25	26	28	30	33
Other professional and out-patient ancillary services	12	12	14	15	17	20	22	25	28	31	34	38
Subtotal	178	175	186	194	205	217	228	241	255	269	285	302
Baseline Revision, July 1999	n.a.	-4	-4	-2	-2	-2	-2	-2	-2	-2	-2	-3
Total	210	208	223	242	252	275	297	326	341	375	407	440
Annual Growth Rate (Percent)												
Medicare+Choice ¹	26.3	14.0	11.7	18.0	-1.3	25.0	16.7	24.7	0.8	22.8	14.6	13.4
Fee-for-Service												
Skilled nursing facilities	8.9	-3.8	1.7	5.3	5.1	6.4	6.0	6.4	6.5	6.4	6.4	6.4
Home health	-	0.8	10.3	-5.8	10.1	6.6	7.2	7.9	7.8	7.4	6.8	6.6
Hospice	14.9											
Hospital inpatient ²	1.0	2.5	8.6	6.3	4.6	5.7	5.3	5.7	5.8	5.7	5.8	5.8
Physicians' services	-2.5	-1.5	5.7	4.7	4.5	4.7	3.9	4.1	4.5	4.6	4.9	4.8
Outpatient facilities	3.0	0.6	4.2	2.3	2.4	3.4	2.6	2.8	3.0	3.0	3.3	3.5
Other professional and out-patient ancillary services	-5.5	-6.6	8.4	8.5	7.1	7.7	7.2	7.4	7.3	7.3	7.6	7.9
All Fee-for-Service	0.7	0.6	14.0	13.0	12.5	13.2	12.3	12.3	12.1	11.0	10.7	10.2
All Medicare Benefits	-2.1	-1.4	6.4	4.4	5.5	5.8	5.2	5.5	5.8	5.8	5.9	5.9
	1.4	-0.8	7.2	8.1	4.1	9.5	7.7	10.0	4.4	10.2	8.4	8.2

SOURCE: Congressional Budget Office.

NOTES: Numbers may not add up to totals because of rounding. n.a. = not applicable.

¹Includes spending for health maintenance organizations paid on a cost basis, certain demonstrations, and health care prepayment plans, which are paid on a cost basis for Part B services.

²Includes subsidies for medical education that are paid to hospitals that treat patients enrolled in Medicare+Choice plans.

The most dramatic change was in spending for home health care, which actually fell by 14.9 percent in 1998. In March 1999, CBO projected that home health spending would increase slightly in 1999. However, it now appears that spending for home health care in 1999 and 2000 will be several billion dollars lower than previously anticipated. The use of home health services seems to have dropped substantially, probably as a result of both antifraud activities and an unexpectedly cautious response by home health agencies to the limit on average payments per beneficiary under the interim payment system. That limit applies to aggregate payments: payments for individual beneficiaries may exceed the limit as long as the average payment for all beneficiaries served by an agency does not exceed the per-beneficiary limit. Some agencies, however, apparently believe that the limit applies to each beneficiary and are cutting off services to patients who have reached the per-beneficiary limit. Thus, the average payment per beneficiary is well below the allowable amount.

Medicare will replace the interim payment system for home health services with a prospective payment system in 2001. That system will remove much of the uncertainty about payments that has contributed to the current apparent drop in use of services, so spending for home health services is expected to rebound in 2001 and later years.

SNF expenditures, by contrast, continued to rise in 1998 but at less than half the rate of growth in 1997—8.9 percent compared with 21.1 percent. The slowdown in spending reflects the implementation of new prospective payment systems and increases in the time for processing claims.

The transition to prospective payment systems is expected to hold down the average annual rate of growth in these categories of spending through 2001. Spending is then projected to increase through 2009 at an average annual rate of 6.2 percent for SNF services and 7.5 percent for home health services.

Inpatient Hospital Services. Medicare payments for inpatient hospital services fell 2.5 percent in 1998, to \$87 billion. The factors contributing to that drop include a decline in the volume of services provided (reflecting the drop in fee-for-service enrollment) and several provisions in the BBA that froze payment rates for most operating costs, reduced capital-related payment rates by 17.8 percent, and cut subsidies for medical education. In addition, the case-mix index fell 0.5 percent in 1998. Preliminary data suggest that the case-mix index is continuing to drop in 1999. Much of that unprecedented drop is probably attributable to widespread adoption by hospitals of less aggressive billing practices following antifraud initiatives that focused on those practices.

For most hospitals, the BBA limits cumulative increases in payment rates for operating costs to about 6 percentage points below inflation in hospital input prices over the 1999-2002 period. CBO projects that the limit on rate increases, in combination with declining fee-for-service enrollment, will result in a 1.5 percent drop in payments for hospital inpatient services in 1999. Those payments are projected to begin rising in 2000, with annual growth rates averaging 4.5 percent from 2000 through 2009.

Physicians' Services. Medicare payments for physicians' services rose 3.0 percent in 1998, to \$32 billion. Payments are projected to remain flat in 1999 and to grow at an average annual rate of 2.8 percent over the next decade, reaching \$43 billion in 2009. That growth rate is a result of payment formulas enacted in the BBA that tie the growth of per-enrollee expenditures for physicians' services to the growth of gross domestic product (GDP) per capita. Those formulas generate annual rate changes that oscillate widely around a smooth trend. CBO projects stable growth rates, however, because the timing of those oscillations is impossible to predict.

Outpatient Services. Payments to outpatient facilities—such as hospital outpatient departments, dialysis facilities, and rural health clinics—fell by 5.5 percent in 1998 and are projected to decline another 6.6 percent in 1999. Those reductions result largely from lower payment rates accompanying the transition to a prospective payment system for hospital outpatient services. Outpatient payments are projected to rebound in 2000 and grow at annual rates of 7 percent or more for the rest of the decade.

Spending for outpatient therapy services and other outpatient ancillary services—including pharmaceuticals, durable medical equipment, and chiropractic care—rose only 0.7 percent in 1998 as a result of reductions in payment rates and a cap on payments for therapy services performed outside hospitals. Projected payments for nonphysician professional services and outpatient ancillary services will grow only slightly in 1999 before taking off again in 2000. Annual spending growth is expected to average 11.3 percent from 1999 through 2009.

EFFECTS OF THE BALANCED BUDGET ACT

In January 1997, CBO projected that net mandatory outlays for Medicare would grow from \$189 billion in 1997 to \$288 billion in 2002. That January 1997 baseline was the basis for CBO's estimate of the savings from the BBA. CBO estimated that the BBA would reduce net mandatory spending for Medicare by \$6 billion in 1998, \$41 billion in 2002, and \$112 billion over the 1998-2002 period. As a result, in its August 1997 analysis of the BBA, CBO projected that net mandatory outlays for Medicare would grow to \$247 billion in 2002, rather than the \$288 billion projected the previous January (see Table 3).

TABLE 3. Comparison of August 1997 and July 1999 Projections of Net Mandatory Outlays for Medicare

(By fiscal year, in billions of dollars)

	1997	1998	1999	2000	2001	2002
January 1997 Projection	189	206	226	250	261	288
Minus Effects of Balanced Budget Act	0	-6	-16	-29	-20	-41

TABLE 3. Comparison of August 1997 and July 1999 Projections of Net Mandatory Outlays for Medicare—Continued

(By fiscal year, in billions of dollars)

	1997	1998	1999	2000	2001	2002
August 1997 Projection	189	200	210	220	241	247
July 1999 Projection	187	190	188	202	218	226
July 1999 Projection Minus August 1997 Projection	-1	-9	-22	-19	-23	-22

SOURCE: Congressional Budget Office.

NOTE: Numbers may not add up to totals because of rounding.

CBO's current baseline, prepared in July 1999, projects that net mandatory Medicare spending will grow from \$188 billion in 1999 to \$226 billion in 2002. Those figures are \$22 billion and \$21 billion, respectively, below the levels projected in August 1997.

Why have the projections changed? Each year CBO updates its budget projections to account for legislative changes, updated economic assumptions, and other new information. Since the enactment of the BBA, the only noticeable legislative effect on Medicare spending has been the modification of home health payment rates included in last year's omnibus appropriation bill (Public Law 105-277). CBO estimated that legislation will increase Medicare outlays by \$2 billion in 2000 and reduce them by \$1 billion in 2001. CBO's current projections of inflation rates are slightly lower than they were in January 1997. Those lower inflation rates account for about \$3 billion to \$4 billion of the annual differences between the August 1997 and July 1999 projections.

Much of the difference between the two sets of projections is attributable to new information—most notably the unanticipated slowing of spending growth in 1997 and 1998 resulting from improved compliance with Medicare payment rules. In essence, the 1997 projections were too high because CBO did not anticipate the full effects of Operation Restore Trust—Medicare's program to combat fraud. CBO also did not foresee the increasing lag in 1998 and 1999 between when services are furnished and when payment is made. In addition, CBO assumed that adjustments to Medicare+Choice payments to reflect the risks of plans' enrollees would be made in a budget-neutral way rather than in a manner that would reduce spending.

CBO has not revised its estimates of the effect of the BBA on Medicare spending. With the possible exception of the projections of the interim payment system for home health agencies, CBO believes that its estimates of the Balanced Budget Act were reasonable.

CONCLUSION

Although Medicare spending has slowed dramatically in 1998 and 1999, CBO expects it to resume growing at an average rate of 7 percent to 8 percent in the decade after 2000. In particular, spending for home health services is likely to rebound after 2000, when the prospective payment system replaces the interim payment system.

Medicare spending is likely to grow even faster after 2010 with the influx of the baby-boom generation into the program. That growth is due both to the unprecedented increase in program enrollment and continuing increases in spending per enrollee. Assuming no change in policy, the Medicare trustees project that Medicare spending will grow from about 2.5 percent of GDP in 1998 to 4.9 percent of GDP in 2030 as the last of the baby boomers enroll in the program. Such an expansion in program spending poses an unprecedented challenge to policymakers and to the country.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Crippen.

Well, we have heard about the decrease in the rate of increases in Medicare spending. Waste, fraud and abuse. Ms. Eshoo certainly spoke regarding the area that you referred to, the coding.

I might add that I have a son who is a primary care physician and when he opened up his practice he could not afford, as I was just telling Ms. DeGette, the computerized system. He had a manual system. So I spent probably the better part of a month in his office trying to work up that system. I thought it would be a great

opportunity for me to learn, too, just the grassroots and that sort of thing. And there was really quite a range in the coding.

As tempted as I was to try to say, "Hey, this coding ought to be maybe something higher," he would not let me do it, and that is why he is struggling today.

But there is quite a range there and you can see where there is an awful lot of room for people to take advantage of it, and I know that HCFA is aware of that.

In any case, we have heard about the money in that area. Obviously we are all concerned. I know HCFA is concerned. We are all concerned with quality care and access to care.

Let me just ask you if you know, and I know Dr. Ross, I think in your statement you made some sort of comment to the effect that there is really no evidence to date that beneficiaries' access to care has been impaired by the BBA. Is that correct, that you made that comment? At least it was in your written statement.

Mr. ROSS. Yes, yes.

Mr. BILIRAKIS. Well, let me ask the three of you if you know, referring now to present access to care and quality of care as affected by BBA and, in addition to that, how you might forecast that in the near future. In other words, it might be good today but you expect that it might worsen or not change in any way whatsoever.

Do you have comments, Dr. Ross?

Mr. ROSS. Well, I think I would like to pick up on one point that Dr. Scanlon made regarding care in skilled nursing facilities, which is to try and relate the claims that we have heard against the reality. MedPAC does not see an issue today, in part because the system is still being phased in. But we are concerned about problems that down the road as we go to 100 percent, if we are not correctly matching costs and payments for the high-acuity groups.

On something like hospital inpatient services, we have been very cautious. We have said for this year's operating update we think the current law is okay. We did not go beyond that because we are taking it, if you will, one step at a time.

I think the thing that is frustrating for all of us, and Mr. Hash this morning alluded to it, is the absence of data to try and get a systematic assessment of what is going on out there.

What we hear a lot about is what is happening to revenues. What we hear much less about is what are the responses to those revenue changes? What is that translating to in terms of lower cost growth, if at all? Are changes in cost growth coming from improved productivity and behavior changes we want or from avoiding certain kinds of beneficiaries?

So our efforts, along with some of the other agencies, are to keep the feelers out, to try to get an assessment, sponsoring surveys, talking to providers, talking to beneficiary groups. I am not sure I want to make a prediction. What I am trying to say is that we are out there looking at it.

Mr. BILIRAKIS. Dr. Scanlon?

Mr. SCANLON. Our response has been that while access is not a widespread problem, the quality of information is such that we cannot be totally convinced that there are not instances where there is an access issue. So it has been always a qualified response.

There is also the aspect of it which is that the systems themselves have not taken into account sufficiently the differences in patient needs and in particular, they have not accommodated the high-acuity patient. It applies to home health. It applies to the therapy caps. It applies to the skilled nursing facilities. Therefore it is very important that the systems be adjusted to try and serve those patients.

Now we agree that as these systems are phased in, the continuing adequacy of resources is a critical issue. There is a question of how much have we built into the base that will allow us to feel confident about that foundation. And, as Mr. Crippen indicated, the rapid growth that was going on before BBA may suggest that we have built quite a bit into that base.

Mr. BILIRAKIS. Mr. Crippen?

Mr. CRIPPEN. Mr. Chairman, just a moment because, as I said at the outset, CBO is less in the business than my colleagues here of looking at the outcomes of policy; we look at the inputs. But I would suggest you may have the most current data, both from being in the districts and listening to providers but also from whatever you are hearing from constituents.

One thing that I have been trying to watch a little—just as an indicator—is how much constituent mail you are getting complaining about the inability to get care under these new rules? And I do not know where that is at the moment. Certainly earlier in the year it was not very prevalent.

But you have so many indicators probably that we do not have. We are dismayed by the lags in the data collection, but you have some current data of your own.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Crippen.

Miss DeGette.

Ms. DEGETTE. Thank you.

Mr. Crippen, following up on this data collection issue, I am wondering; I have heard all of you say we have inadequate data; we just have either one side or we have anecdotal evidence.

What is the status of this data collection and what are we going to do in the meantime?

Mr. CRIPPEN. I will jump in here and tell you where we think it stands. There is always a lag in the data by a year or 2—18 months. That lag is a little bit longer even now—unfortunately at a critical time when these policies are going into effect—because of all of the other activity going on to get computers compliant and all of that, with the turn of the century.

So it is worse than usual at a time when you would like it to be better than usual. So we are relying, in part, on anecdotal evidence, although we are getting bits and pieces of a larger picture.

As I said, if you look at the instant data we can get on how hospitals are coding diseases as I suggested, it seems to be that there is now what is euphemistically is called downcoding or a reverse creep. Over the years, the case mix-adjuster had been going up, and now it is going down. That is fairly contemporary data, so it suggests, as part of a larger picture, but it is not a complete picture.

Ms. DEGETTE. Thank you.

I want to, Dr. Ross, ask you a question because you talked about the hospitals and you were kind of lumping the hospitals together, talking about the effects on them. I guess I would note we have different kinds of hospitals. We have the for-profit hospitals, we have the public hospitals, the children's hospitals, we have the rural hospitals, and it seems to me all of them probably have different impacts and they probably have different needs.

Would that not be accurate?

Mr. ROSS. Absolutely, there are different classes of hospitals. We also pay them in a number of different ways—operating capital, outpatient.

Ms. DEGETTE. Okay, because one thing I have noted is that you folks say that implementing this outpatient prospective payment system is going to reduce payments for virtually all hospitals but it is going to have a much larger effect on specific kinds of hospitals.

Is that accurate? And, if so, which kinds of hospitals?

Mr. ROSS. I am basing that statement on estimates that Health Care Financing has done in conjunction with its proposed rule on this, but it is on small, rural hospitals, it is on the cancer hospitals that you have heard about, it is on the teaching hospitals.

Ms. DEGETTE. So would it not be fair to say, then, that the outpatient PPS is somewhat uncertain at this point, since it has not been implemented Mr. ROSS. As we have learned with BBA in general, that is true of any prospective system coming on line. One of the impacts possibly of the outpatient system that contributes to the uncertainty is how hospitals will respond now that they need to code for the purposes of payment, which they have not before.

There is some feeling that as hospitals learn to code appropriately for the new system, some of those estimates of the reductions may be a little overstated.

Ms. DEGETTE. Now how is this data collection issue going to impact on our knowledge of the effect of the coding and how fast that is being implemented? I mean is there a lag there?

Mr. ROSS. There will be a lag there, as well.

Ms. DEGETTE. How long is that lag?

Mr. ROSS. I cannot answer that but I presume it will be probably a couple of years, again depending on how much is done in terms of a phase-in and what that phase-in looks like.

Ms. DEGETTE. See, the problem I have is here we are. We are trying to pass laws, the administration is trying to enact regulations and when we have these data lags, we are really legislating in a vacuum.

I do not know if you are even the appropriate people to ask but do any of you have any thoughts how we could reduce this lag time?

Mr. SCANLON. I think we have been trying, both MedPAC and GAO, in terms of looking at the outcomes of these policies to try and supplement the lack of data that comes from the administrative systems with the different surveys that we have done and the Inspector General has undertaken similar kinds of efforts.

The problem in doing that is that those are labor-intensive activities in which we are able to contact relatively small numbers of providers.

Now I hope, in some respects, you can think about these efforts as representative anecdotes. We go out and get random samples of anecdotes, but it does not guarantee for us that there are not other areas in which if we went there, we might identify a problem.

This is the best information that we can provide you at this point in time.

Ms. DEGETTE. Are you doing anything specifically to improve the data collection?

Mr. SCANLON. Well, we are doing this type of survey effort. We have done it for home health agencies, which we finished in the early summer. We are doing it now for skilled nursing facilities. We are working to be able to use the information coming out of the administrative claims systems for home health as soon as it is available by processing the pre-BBA experience, rather than waiting until new data are available.

We issued a report in May that used the most currently available data on home health and reported on the first quarter of 1998. So we are going to try to get you an update as soon as the data become available.

Ms. DEGETTE. Maybe we will do the second quarter.

Mr. SCANLON. Well, we like to aim higher than that.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you. Mr. Burr?

Mr. BURR. Let me ask all of you to comment on the general question of have our savings in Medicare been greater than those estimated when we passed BBA 1997?

Mr. CRIPPEN. I should probably take that one since we did the original estimates. Medicare spending is certainly lower than we anticipated, even after the BBA's passage and there is a table in my testimony, Table 3, that shows you what we thought would happen before and after BBA and what really did happen, at least up until this point. And the summary statement is that Medicare spending is about \$20 billion lower a year than we anticipated post-BBA.

But that does not necessarily say that there are more savings in the policy that you passed. It does turn out that Medicare spending is less than we expected, but as akin to in 1997, as you know, we were not expecting post-BBA to have these kinds of surpluses facing us.

So without a change in tax law, we are still getting a lot more revenue than we thought. What has changed is underlying behavior, not necessarily the policy change that you voted for in 1997 on this or anything else.

Mr. BURR. Define "underlying behavior" to me.

Mr. CRIPPEN. Well, in the case of Medicare spending, we think—and again have some anecdotal evidence to suggest that—the widespread and very public attacks on fraud—and again that is not to say that all of the change is because there was that much fraud but it is the reaction of providers to those efforts that have made people more cautious. It slowed down the processing, causing people to be more careful about the claims being filed. In the case of hospitals, it looks like there has been some diminution in the coding to less expensive treatments or less expensive DRGs.

Mr. BURR. Utilization is up or utilization is down?

Mr. CRIPPEN. Of?

Mr. BURR. Health care.

Mr. CRIPPEN. I am not quite sure. How one measures it is not quite clear to me.

Mr. ROSS. It is up in some areas and it is down in others. We have seen fewer claims, for example, for home health services; we know that. I believe physician services, that the volume is running about as one would project.

Mr. SCANLON. One of the things that is very difficult to understand is that some of these patterns, if you look at the period before the Balanced Budget Act and you look at the home health, there were areas of the country in which the use of services was declining when there were no constraints on the system and there were other areas where it was growing rapidly and there was no sense that there were differences in the beneficiary populations in these different areas.

So one of the things that we have not been able to do is explain why growth was going on before the Balanced Budget Act and what we have not been able to do for you yet is explain what has happened since then.

What we have seen is a narrowing of the differences across those areas, which is consistent with what the Balanced Budget Act was attempting, but at the same time, we cannot tell you what is the right level and whether we are achieving it or not achieving it in particular areas.

Mr. BURR. A reduction in home health could be because some people tightened their policies because of the fraud and abuse fear. It could be because some entities do not offer the services in the same way that they did before. It could be because seniors are not utilizing the services that are available to them at the same rate, correct?

Mr. SCANLON. All those are possibilities.

Mr. BURR. All those are possibilities and we do not know exactly the percentage each one plays, correct?

Mr. SCANLON. That is correct.

Mr. BURR. CBO did a reestimate in March on home care and found an additional \$56 million of savings over and above what you had projected January 1998, which was \$75 billion worth of savings.

If you did a report January of the year 2000, what do you think that you would find?

Mr. CRIPPEN. At the moment it would appear that our estimates of home care spending that we made last spring appear to have been too high again and that they will be lower this year than we had projected back in the spring.

Mr. BURR. And are you able to yet draw any conclusion as to why that spending would be less than what you projected?

Mr. CRIPPEN. We do not yet have good clear conclusions.

Mr. BURR. But it would fall in the three categories that we just talked about?

Mr. CRIPPEN. Oh, yes. Part of this, too, is in the implementation. There are some agencies—and I cannot tell you exactly how widespread it is—maybe some of my colleagues can—in which the constraint that is being asked of the home health industry is based on

an average per-patient cost, and it is being applied to each patient, rather than on an average in some cases. So that obviously will give you a much lower average cost.

So there are some implementation issues, as well, going on out there but clearly we got wrong in the case of home health how much the policy would produce in terms of savings. But, as I am suggesting, there are lots of other things going on out there, as well, in addition to BBA.

Mr. BURR. Let me just ask the last question for all three of you to comment on.

Is it important for an agency when they implement policy to have knowledge of what the congressional intent was and should that be included in their process of how they proceed on that legislation? Or is everything 100 percent left up to their interpretation?

Mr. ROSS. I am not sure you have the right panel here.

Mr. SCANLON. I think you need our general counsel.

Mr. BURR. You will be sufficient.

Mr. SCANLON. My personal sense is that certainly an agency needs to take into account the sense of Congress in this. Now the issue, of course, is how to establish clearly the sense of Congress. And I do know that they attempt to be extremely faithful to the statutory language. At least in my mind it has an extreme weight attached to it.

But I do think a response from the general counsel would be appropriate for you and we would be happy to get it for you.

Mr. BURR. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Welcome back.

Mr. BROWN. I apologize for having to leave.

There have been, I think perhaps in our districts, Mr. Burr has talked about being home and Mrs. Cubin and the chairman and all of us, about what we heard in the August recess and prior to that. At least in my case and I think in some others, we seem to hear perhaps the most from physical therapists and occupational therapists and speech therapists in what the caps, the \$1,500 caps have meant to them.

Some survey said that some 13 percent, one out of seven beneficiaries who need rehabilitative therapy will exceed the cap in a given year.

Has GAO, Mr. Scanlon, examined the potential impact of the cap on beneficiaries, the \$1,500, and the combining of speech and physical therapists and what that has meant?

Mr. SCANLON. We looked at it but as in other issues, we have been handicapped by the lack of current information regarding users of the cap. But the study that you referred to was actually done by MedPAC and it did involve looking at who would exceed the cap.

However, the cap does not apply to people who use outpatient departments. So a smaller share than 14 percent is actually going to be affected in terms of not being able to access coverage, since outpatient departments are the largest source of therapy services.

It is only if you were to seek services from an independent therapist or agency that you would be affected by the cap.

Furthermore, there is an issue that exists today, which is that HCFA has not been able to implement the cap as specified in the BBA in that because of the year 2000 computer problems, they have had to rely on voluntary compliance by providers. So it is providers' responsibility not to bill beyond \$1,500. That does not mean that a beneficiary cannot go to another provider and have services billed for by that other provider.

Mr. BROWN. Do you have evidence that that is happening?

Mrs. CUBIN. If there is another provider.

Mr. SCANLON. There is no information one way or the other on that.

Mr. BROWN. Do any of you have an opinion on aggregating the three and setting a figure so that there is more independence or more leeway in making rehabilitative decisions?

Mr. SCANLON. I think our feeling is that the most important step here is to make this cap, if there is going to be a cap, based on clinical criteria so that differences in patient needs are taken into account. A cap that is generous enough to provide therapy to people with more extensive needs may be very much too generous for people with very minimal needs. It provides no control over utilization.

One of the concerns about this service, as many other services, is that the pattern of growth before the Balanced Budget Act is inexplicable. The independent agencies that exist in providing therapy are overwhelmingly concentrated in very few areas of the country. Most of the rest of the country is relying upon outpatient departments and home health agencies for their services.

Why there has been this concentration and why there was so much growth on the part of these agencies was something we did not understand but we were concerned about. So the idea of imposing some controls seems to make sense.

Mr. ROSS. If I could follow up on that, MedPAC does not have specific recommendations on the caps but I just wanted to sort of draw the parallel here with what has gone on in home health, where once again you implement a payment system. It was not an individual-specific cap but an agency-specific, per-beneficiary cap, with no adjustment for case mix, for differences among individuals. And we see what we get there and you can anticipate similar situations here until you get the payments somehow or other to reflect differences in needs among the beneficiaries.

So I think I can speak for the commission, saying that we are supportive of that in all instances, that we want to take health status into account.

Mr. BROWN. The home health IPS and the PPS for skilled nursing homes, I hear over and over seem not to adequately cover the cost of caring for the sickest patients. Is it wise to continue implementing these new payment systems, given that fact, the fact that the sickest seniors may not receive the care they need? So should we discontinue? Should we change? What should we do?

Mr. SCANLON. I do not think we should discontinue. I think we should work very quickly to refine. HCFA is aware of the problem with the skilled nursing facility prospective payment system and has commissioned work in order to identify how to adjust the rates to deal with the higher acuity patient, and we think that that needs to be done as quickly as possible.

And fortunately, the interim payment system is scheduled to be replaced by the prospective payment system for home health, which will be able to discriminate in terms of patient needs and to adjust rates.

Now I will not add to that sentence at this point accordingly until we see the system and until we know that it is going to be able to deal with the differences in patient needs; until then we cannot be satisfied.

Mr. BROWN. Comments from the other two of you about that?

Mr. CRIPPEN. I would just say again that my colleagues know more about the outcomes than we do, but the payment system for the skilled nursing facilities, for example, is based on 1995 data, although grown for other factors. But if the case mix of a particular provider has changed, particularly if the patient load has gotten more expensive, more expensive kinds of clientele, then the 1995 base will not represent adequately a payment structure for them.

So again it is another way of saying what my colleagues have. We need to be able to apply a case mix adjuster in order to update a base year, whatever year we choose it to be.

Mr. ROSS. And just on the home health, on the IPS, we MedPAC has noted that the timetable is pretty tight for getting the prospective payment system in and as Dr. Scanlon says, we still have to wait and see what it is before we will know how well it is picking up on the high end. But our commission has recommended giving some kind of consideration to an outlier system, at least under IPS, if for any reason it were to continue, and we have outliers under PPS for inpatient hospital, too, for truly expensive cases that go beyond what you can get out of your case mix adjuster.

Mr. BILIRAKIS. Ms. Cubin.

Mrs. CUBIN. Thank you, Mr. Chairman.

First of all, I want all of you to know that I understand that the Congress passed a law that you have to implement. So please know that my frustration is not directed at you. I guess it is more directed at what I consider to be a lack of understanding of conditions in areas like the area that I live in.

I wanted to ask Dr. Ross first of all, was your response to Congresswoman DeGette that the largest cuts would be made in rural hospitals and a couple others, but rural hospitals specifically?

Mr. ROSS. These are the HCFA projections for implementation of the PPS. Not the largest would be for small, rural hospitals but they would be only among the classes of facilities that have large reductions.

Mrs. CUBIN. Okay. And forgive me for skipping around. I have been scribbling these questions all over the place.

The government has accepted the concept in other areas that every person in America is entitled to some services. Let's take the telephone, delivering the mail. We all pay the same for postage. Even though it costs more to deliver on postal routes in Wyoming where the route might be 150 miles, as opposed to a 20-block area, we all pay the same amount. Electricity, everyone is entitled to electricity, even though we have to have a universal service fund.

What I am submitting to you is that I realize that costs in rural areas are higher because they are not as efficient as in urban areas and yet the policy that has been followed as far as health care is

concerned does exactly the opposite. It cuts money from rural health care providers, whether it is an agency or a physician or whatever.

Let me tell you what we do in exchange for that, by the way. Where do you put the nuclear waste that is generated? We do not get one kilowatt hour of electricity from nuclear power in Wyoming or in Idaho—I guess Idaho might get a little—but nonetheless, where do those spent rods go? They go to us.

So it all balances out in the end. And I think in a lot of areas the government, the administration—not this administration, all administrations—have seen the light that it is not ever going to be as effective, as efficient to provide services in rural areas as it is in urban areas, but nonetheless, people in rural areas have the same right to quality medical care that they do in urban areas.

I want you to know for a fact, one of the reasons—and Mr. Crippen, you said that one of the reasons you think that the Medicare expenditures are less is because there has been less fraud and abuse. Well, I am going to tell you what. The hospitals in Wyoming that are so small, when they get a letter from the Department of Justice or a doctor, they get a letter from the Department of Justice presuming they are guilty, saying, "If you don't pay up front, then the consequences are going to be way worse than if you had if we find out that you were wrong."

In Wyoming I say it is probably the only place on earth where you can make a long distance call, get the wrong number, and not only will you know the person that you reached but they will be able to give you the right number.

My point is in Wyoming I do not believe that there is very much fraud. I believe that there could be a small amount of abuse with certain providers but a small number. And I believe that there can be mistakes made, and yet we are literally facing closing of nursing homes, closing of day care centers for adults.

Dr. Ross, when you said that your findings are that Medicare patients could find doctors, not in Wyoming. That is probably true—I believe you—in urban areas where there are plenty of doctors. But in Wyoming where there are not enough doctors, my husband is a primary care physician. He has not taken a single Medicare patient that he charges for—he has taken some that he takes care of for free—that he charges for for years.

So I have questions that I am going to submit. One of them is I want you to justify for me the difference in the allowable Medicare charge between urban areas and rural areas. Maybe these are questions I should have asked Mr. Hash but I would really like to work with you to just explain the differences that there are between trying to provide health care in urban areas and rural areas.

I do not think we need a hospital in every community, even though every community would like one, but we do need telemedicine. And now, with the cuts that are made in education, even the family practice centers that we have that take care of people who cannot get doctors otherwise are threatened with being closed.

I do not think that it is in any way negligence on your part that you are not aware of these critical situations, but I do think you are not aware of them.

So you can each say something because I waited all this time to have my say and I did not even ask one question. I have a bunch.

Mr. ROSS. I will just say you raise a lot of important issues and I will be happy to work with you on them.

Mrs. CUBIN. Thank you.

Mr. SCANLON. We would be very happy to respond to your questions and also to provide you some of the work that we have done, which has—we have tried to take into account the particular circumstances, the unique circumstances of rural areas.

In the work that I talked about with respect to home health care, our primary focus was on rural areas, feeling that in an area where there are either no agencies or one agency, that the impact of the BBA changes could have been extremely different than in an urban area.

So we are sensitive to it but there certainly needs to be a lot more work done on the issue.

Mrs. CUBIN. One last thing I want to say. You talked about the \$1,500 cap on physical therapy and occupational therapy, that it was per provider. In Wyoming sometimes there is only one provider in a county that is bigger than the size of Maryland and Pennsylvania put together. Only one provider.

Mr. SCANLON. That is a reality. The hospital outpatient department is probably the major safety valve for rural areas because they are not affected by the cap.

Mrs. CUBIN. But our physical therapists in many cases are not affiliated with the hospital. But my time is up and the chairman is giving me this look.

Mr. BILIRAKIS. It is up.

Mrs. CUBIN. Thank you very much.

Mr. BILIRAKIS. That is the first time she has ever been concerned about the chairman's look.

Dr. Scanlon, you referred to the increases in the past in Medicare costs and you used the word "inexplicable." Can these fixes, the needed fixes, the fair fixes, take place without the concern, fear, risk, whatever the proper words might be, of going back to the inexplicable?

Mr. SCANLON. I think they can. I mean I think it is important that we think about the structure that we have identified in the Balanced Budget Act and understand how to refine it so that it produces the desirable outcome. We do not want to go back to the structure that we had before the Balanced Budget Act, which were systems which had incentives in there to produce excessive spending and we saw the response being very consistent with those incentives, and we do not want to return to the pre-BBA days. We want to refine what we have now to make sure that the program works effectively.

Mr. BILIRAKIS. Well, thank you. I know that everything goes through CBO up here. The power that you guys have is amazing. You know, we do these things, BBA 1997, feeling that we are doing the right thing and for the most part, I think it was, but there is an awful lot of unexpected harm that took place, too. So I would hope that you would be a part of anything that we might do can we can use your wisdom in that regard.

As per usual, we will have a number of written questions to you. I know that you are willing to respond to them. Again as you heard earlier, we are sort of on hopefully a fast path here, so obviously the quicker we get the responses, the more help they can be.

And I would also say that Mr. Gustafson and others of HCFA are in the audience, have listened to your testimony. He has made an awful lot of notes back there, Tom has, so hopefully you will have been of even more help than ordinarily. Thank you very much for being here.

The third panel, finally, and these people are always disadvantaged as the last panel because by then, half the audience is gone or more and hardly any members are here. You are very, very important people to what we are trying to accomplish nevertheless.

Mr. Gail L. Warden, President and CEO of Henry Ford Health System, Detroit, Michigan. He is here on behalf of the American Hospital Association. I do not know whether Mr. Dingell—I know he is trying to get here. He is on his way and he would like to make his own introduction, I am sure.

Miss Sally Rapp, independent owner of Saint Francis Extended Care, Pleasanton, California on behalf of the American Health Care Association. Miss Nancy Roberts, President and CEO of the Kent County Visiting Nurse Association, Warwick, Rhode Island on behalf of Visiting Nurse Association of America and National Association for Home Care.

Dr. Richard F. Corlin, speaker of the House of Delegates, American Medical Association. And Mr. David P. Holveck, CEO of Centocor, Melvern, Pennsylvania on behalf of Biotechnology Industry Organization.

Again your written statement is a part of the record. We will put the clock at 5 minutes. Hopefully you can stay within that. And again our apologies for your sitting in that audience so very long. But again HCFA is here and they will be listening to you, in addition to us.

So I guess I am going to start with Miss Rapp if I may, because Mr. Dingell is not here please. Miss Rapp, if you would proceed, please.

STATEMENTS OF SALLY RAPP, INDEPENDENT OWNER, SAINT FRANCIS EXTENDED CARE, ON BEHALF OF AMERICAN HEALTH CARE ASSOCIATION; NANCY ROBERTS, PRESIDENT AND CEO, KENT COUNTY VISITING NURSE ASSOCIATION, ON BEHALF OF VISITING NURSE ASSOCIATION OF AMERICA AND NATIONAL ASSOCIATION FOR HOME CARE; RICHARD F. CORLIN, SPEAKER OF THE HOUSE OF DELEGATES, AMERICAN MEDICAL ASSOCIATION; DAVID P. HOLVECK, CEO, CENTOCOR, ON BEHALF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION; AND GAIL L. WARDEN, PRESIDENT AND CEO, HENRY FORD HEALTH SYSTEM, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION

Ms. RAPP. Thank you, Mr. Chairman and members of the committee for allowing me to appear here today. I would like to share with you concerns that I have about the impact of the 1997 Medicare cuts on patients, their families and skilled nursing providers like myself.

My name is Sally Rapp and I am the owner of an independent skilled nursing facility in Hayward, California. I am here today on behalf of the American Health Care Association, which represents 12,000 long-term care providers.

Mr. Chairman, balancing the budget and controlling Medicare spending are laudable goals but we should not, we must not balance the budget on the backs of our Nation's frail and elderly citizens.

As you already know, the unintended consequences of the 1997 budget deal are being felt in every corner of America by Medicare beneficiaries, their families and caregivers. Studies show that Medicare cuts have been much deeper than Congress or the administration expected.

As a result of these cuts, stroke patients are being forced to choose between learning to walk again or talk again. Amputees are being denied access to therapies that doctors consider essential to the rehab process and that these patients certainly consider essential to being able to simply walk again. And patients with the most medically intense needs are waiting in hospitals for days, sometimes weeks, to find a skilled nursing facility that can deliver necessary care. Often these patients are forced to use a facility far away from families or loved ones.

Policymakers on both sides of the aisle agree that the Balanced Budget Act, in the way that it has been implemented, is a major and detrimental effect on Medicare beneficiaries. Sixty-five senators have written to President Clinton acknowledging the severity of these cuts. The well respected chairwoman of the Medicare Prospective Advisory Commission, Gail Wilensky, has said and I quote, "Congress and Medicare officials should devise some way of increasing payments to nursing homes for patients who need the most costly and extensive care." I am here to urge you to take that action this year.

I would like to give you just one example of how these cuts are affecting Medicare beneficiaries. Linda Jorgensen, who is in the audience today, is faced with the very real and painful effects of the arbitrary \$1,500 therapy caps as she watches what they are doing to her father. Linda is from Springfield, Virginia. Linda's father Victor, a steelworker and a decorated war veteran, is battling Parkinson's disease, the effects of a major stroke, and an unsympathetic Medicare policy.

Her father is a resident of Potomac Center, a skilled nursing facility in Arlington, Virginia. Before the Medicare cuts took effect, he had been on an intense regime of physical, occupational and speech therapy. But in February of this year Linda learned that he had already used two-thirds of his annual allotment of therapy under the new Medicare caps. Reluctantly, she and her father's neurologist agreed to stop the therapy to ensure that they did not exceed the caps too early in the year.

In Linda's case, her foresight was extremely warranted. Just a couple of weeks ago in the beginning of September, her dad needed speech therapy for a swallowing problem. Ironically, Victor met his \$1,500 cap just yesterday. Now Linda and her family are being forced to pay for his essential speech therapy out of their own pocket.

Linda regards the caps as unfair and inhumane. I regard the caps as unfair and inhumane. How many Medicare beneficiaries like Linda's father are there across the country? How many people who expected Medicare to be there when they needed it have been let down, abandoned by the system that they have supported their entire lives since its inception? And for how long can we ask providers to continue providing uncompensated care?

The other challenge we face is the new prospective payment system for skilled nursing care. Implementation is having a dramatic impact on patients and families, forcing lay-offs of tens of thousands of caregivers across the country. As you know, we are concerned that the situation has worsened to the point that many facilities will opt out of the Medicare program.

I would like to comment briefly on the recent report from the Office of Inspector General that Mr. Hash commented on earlier this morning examining the issue of access to skilled nursing care.

Despite the report's misleading headline, it shows quite dramatically that there is a serious problem with access to skilled nursing care. Perhaps most important is the report's finding that nearly 60 percent of hospital discharge planners agree that patients requiring extensive services have become more difficult to place in nursing homes in the past year.

Our industry, like most industries, agrees to shoulder its fair share of cuts to help Congress achieve its goal to balance the budget. I do not think anyone on this panel this afternoon is asking that the \$115 billion be restored to the system. However, the solutions I am proposing today are targeted to where the Balanced Budget Act has put patients at risk.

The bottom line is that the deep cuts in Medicare create a clear and present danger to the Nation's elderly. The problems are critical and require immediate attention. Let me outline what we believe to be responsible solutions to these problems.

Mr. BILIRAKIS. Can you—

Ms. RAPP. Quickly, I will.

First, Congress should pass H.R. 1837, legislation introduced by Congressmen Burr and Pallone, to trigger exceptions to the caps for those beneficiaries most at risk, like Victor. I would like to express my sincere appreciation to Congressman Burr and Congressman Pallone for their leadership on this.

Second, Congress, HCFA and MedPAC all recognize the new payment system for SNFs fails to account for certain Medicare beneficiaries with high acuity conditions. Therefore Congress should enact Senate Bill 1500, which would address the disparity between the cost of providing medically complex services and funding Medicare currently provides.

Finally, Congress and the administration should take steps to ensure that the transition to the new Medicare payment system does not unintentionally disadvantage providers or seniors. Simply put, providers should have the option to go to the Federal rate.

Mr. Chairman and members of the committee, thank you for the opportunity to address you here today.

[The prepared statement of Sally Rapp follows:]

PREPARED STATEMENT OF SALLY RAPP, OWNER, ST. FRANCIS EXTENDED CARE, ON
BEHALF OF THE AMERICAN HEALTH CARE ASSOCIATION

Thank you, Chairman Bilirakis and Members of the House Committee on Commerce, for allowing me to appear before you today. I would like to use this opportunity to share the concerns of skilled nursing facility (SNF) providers as we navigate our way through the challenges of the recently implemented Part B therapy caps and the new SNF prospective payment system (PPS) brought about by the Balanced Budget Act of 1997 (BBA).

My name is Sally Rapp, and I'm the owner of an independent nursing facility called St. Francis Extended Care in Hayward, California. I speak today on behalf of the American Health Care Association (AHCA), a federation of 50 affiliated associations representing over 12,000 non-profit and for-profit assisted living, nursing facility, and subacute care providers nationwide.

Mr. Chairman, controlling Medicare spending is a laudable goal, but the unintended consequences of the most recent cuts in Medicare have been severe on patients, families and care providers. Two major policy changes have hit the skilled nursing facility community with a "one-two punch" from which some providers may not recover. Even more important is that in many cases, Medicare beneficiaries who need care in nursing facilities are not getting access to that care.

The arbitrary cap on Part B therapies set at \$1500 per year has affected residents across the country in ways that clearly were not foreseen. The combined \$1500 limit on speech therapy and physical therapy and the additional \$1500 cap on occupational therapy are threatening patient access to life-enhancing care. This is best illustrated by looking at a real life examples of how a Medicare beneficiary's life has been changed.

First, I'd like to recognize Linda Jorgensen, who is in the audience with us today (recognize). You may have seen Linda and her father on some recent television ads discussing the challenges patients and families are facing as a result of the deep 1997 BBA cuts.

Linda, a federal worker from Springfield, Va., has been forced to suspend rehabilitative therapy for her father, a retired steelworker and decorated war veteran. Linda's father is battling Parkinson's disease, the effects of a major stroke and an unsympathetic Medicare policy threatening the care he needs and deserves. A resident of Potomac Center, a skilled nursing facility in Arlington, Va., her father had been on an intense regime of speech, physical and occupational therapy. But, in February, Linda learned he had already used up two-thirds of his annual allotment under the new caps.

Reluctantly, she and her father's neurologist agreed to stop the therapy for fear her father would need it more later in the year. She says she can't afford the therapy herself. Now, she says, her father's limbs are becoming more rigid and he is in danger of losing mobility.

Linda regards the caps as inhumane. And she is on a personal campaign to let policymakers know.

Another example involves an 85 year-old woman named Frances. Frances owned her own hat making shop here in Northwest Washington. Frances had a stroke early this year and suffered from right-side paralysis as a result. She could not walk, speak, or take care of herself in her activities of daily living such as bathing, eating, dressing, or toileting. She received physical therapy to teach her how to walk again, and was able to walk from her room to the TV room with a walker and a nurse aide behind her. Her speech therapy was helping her to relearn how to swallow and speak again. Unfortunately, she exceeded the \$1500 cap on June 23rd, and now the facility provides care to her without reimbursement and tries to stretch its resources to prevent any decline. Frances also received occupational therapy which taught her how to take a bath by herself, get dressed by herself (with help in the room if needed), and toilet by herself. She had regained independence in her life. Unfortunately, Frances has also exceeded her occupational therapy cap and is now in danger of losing some of the skills and quality of life she had gained. The facility is doing the best it can to care for their residents, but 10% have exceeded the speech/physical cap and about 5% have met or will exceed the occupational therapy cap. Care for our nation's frail elderly is being rationed, and in many cases they are not getting the amount of therapy they need. If after meeting the cap, a resident falls, is hospitalized and needs skilled therapy in the same calendar year, he/she could face a serious access problem in finding a home that will care for them for free. Let me express my appreciation to Congressmen Burr and Pallone for their leadership on addressing this problem. Medicare beneficiaries would benefit if Congress would pass S. 1837, legislation introduced by Congressmen Burr and Pallone. This legislation would address the arbitrary and capricious nature of the \$1,500 an-

nual caps on Part B outpatient rehabilitation services imposed by the BBA. These caps were included without the benefit of data or hearings. Mr. Chairman, I assure you—speaking from the front lines of the skilled care community, no one who was part of this process could have intended this cap to create the kind of patient impact we're seeing. Mr. Burr and Mr. Pallone's legislation would create criteria to trigger exceptions to the caps for the sickest and most vulnerable Medicare beneficiaries. We implore you to pass the Burr/Pallone bill (H.R. 1837) to allow for some exceptions for these caps.

The second blow of the one-two punch is the new prospective payment system (PPS) for SNFs. Implementation of the new PPS has had a dramatic impact on providers of skilled care. With a transformation of that magnitude, the need for corrective adjustments along the way is inevitable. I come before you today to relay our concerns—and more importantly, to propose solutions.

Let me bring to your attention a recent report from the Office of Inspector General (OIG) examining the issue of access to skilled nursing care. Despite the reports misleading headline and unsubstantiated conclusions, the report shows *fairly dramatically that there is a serious problem with access to skilled nursing home care caused by the 1997 Medicare cuts*. Here are some facts from the report:

- "When asked which types of patients have become more difficult to place in nursing homes, the majority of discharge planners (58%) identify patients who require extensive services," according to the OIG. "These types of patients typically complex direct nursing care and expensive medications. They include patients who require intravenous feedings, intravenous medications, tracheostomy care or ventilator care," the report says.
- One-third of all hospital discharge planners said it was difficult to place Medicare patients in SNFs.
- Sixty-five percent of hospital discharge planners say PPS has had an effect on their ability to place patients.

One thing is clear: nursing homes are reevaluating the extent to which Medicare resources will allow them to appropriately care for the sickest patients. The result is a very real access problem to skilled nursing services, specifically proven by the OIG's own report, which is causing backups in hospitals throughout the country. This squeeze has put SNFs in a difficult situation, and we are concerned about the impact it will have on Medicare beneficiaries—specifically high-acuity patients. Yet, Mr. Chairman, the OIG's release of their report is a significant development because they've served to prove the point that major dislocations have occurred as a result of the PPS and its subsequent implementation. Naturally, SNFs will be hard-pressed to continue to provide service when patients' costs of care exceed the resources available.

I want to share with you a few examples of the difficulties SNFs are experiencing under PPS—reports from the front-lines, if you will, in the skilled nursing field—to illustrate the seriousness of the problems we face, and the real threat of reduced access to skilled care.

In Florida, Mrs. Y (89 years of age) arrived at a Lakeland SNF on March 25th to recover from pneumonia and a chronic urinary tract infection. Due to her weakened condition she needed respiratory, physical, occupational and speech therapy plus IV antibiotics to gain the strength she needed to go home. Mrs. Y returned to her home on May 17th thanks to the excellent care she received at the skilled nursing facility; however, the Medicare system failed to reimburse the skilled nursing facility \$20,000 worth of direct and ancillary care that were provided to Mrs. Y, so that she could return to health. This included \$3,000 of pharmacy costs alone. And even though Mrs. Y was in a high Medicare resource utilization group, she consumed over \$350 more a day in respiratory, IV and other therapies than Medicare paid for. Yet, if she did not get that care, she would have used up her Medicare days, then been forced onto Medicaid and probably stayed in the home indefinitely. Staff at the center report that nearly half of their Medicare discharges in a typical month consume an average of \$8,000 to \$10,000 in uncompensated care. Since the facility's policy is to take all Medicare recipients regardless of acuity level, the center's viability is continuing to be severely impacted by the BBA.

In Delaware, Mrs. D, an 85 year old woman, who was recently recovering from an infection and heart problems in a Delaware hospital. She was ready for nursing home placement but, because of Medicare cuts, she had difficulty locating a bed in a SNF, and, as a result, she was forced to stay in the hospital an extra two weeks. Eventually, a provider offered to take her to a center in neighboring Maryland despite the fact that she needed an expensive IV antibiotics at a cost of \$410 a day. Her Medicare level dictated the center would only be compensated \$260 a day for her care. Since then, her doctor has also prescribed a \$1,700 knee brace for which the center will not be compensated.

In the state of Washington, a locally owned and managed independent provider operates a 30-bed skilled nursing facility with a nearby hospital. The facility primarily serves short-term (usually less than 20 days) high-acuity patients—many of whom were patients in the hospital's oncology department. The facility enabled patients to be treated by the hospital's doctors and eliminated the need for these very sick patients to travel between facilities.

The result of PPS on this facility is unmanageable losses of between \$20,000 and \$40,000 per month. The unit is well-managed and has provided uninterrupted high quality care, but it cannot overcome the fact that so many of its patients are very high acuity and require, in many cases, expensive treatments and medications that are not compensated through the PPS rate. If Medicare cuts are not restored, the facility anticipates it will be left no choice but to close its doors, creating access problems for its local Medicare beneficiaries. Additionally, the facility's functions will have to be assumed by another facility several miles away.

The Medicare cuts that are denying beneficiaries access to care are not just affecting Medicare beneficiaries, but also are affecting our employees as well. The bleak outlook for SNFs—the “open-season on caregivers” mentality that seems to prevail in some quarters—is turning away high quality professional staff. These deep cuts have forced layoffs of tens of thousands of employees. Mr. Chairman, the job of skilled care staff is challenging under any circumstances—but I can say with certainty that these dramatic reductions add a new degree of difficulty in providing access to high-quality care that Medicare beneficiaries expect and deserve.

As you know, we are concerned that the situation has worsened to the point that many facilities will opt out of Medicare altogether. These cuts are forcing both independent providers and large national corporations to make difficult choices of whether to provide services in a system that does not provide adequate resources for care. This means that Medicare beneficiaries will have less access to needed care.

Mr. Chairman, the bottom line is that the deep cuts in Medicare create a clear and present danger to the well-being of our nation's elderly. The problems are critical and require immediate attention. I would like to outline what we believe to be fair solutions to four critical challenges—solutions that take into account the constraints of Congress and HCFA in implementing change.

First: Medicare beneficiaries would achieve great relief if Congress would pass S. 1837, legislation introduced by Congressmen Burr and Pallone. Let me, again, express my sincerest appreciation to Congressmen Burr and Pallone for their leadership on this.

Second—Congress, HCFA and MedPAC all recognize that the new payment system for SNFs fails to account for certain Medicare beneficiaries with medically complex conditions. That is especially true for patients with high utilization of non-therapy ancillary services, such as prescriptions, respiratory care, IV antibiotics and chemotherapy. AHCA supports S. 1500, the Medicare Beneficiary Access to Quality Nursing Home Care Act. To date, there is no House companion, but we hope the House will follow the lead of Senators Hatch, Domenici, Kerrey, and Daschle, by supporting similar legislation. S. 1500 would identify where there are high-cost patients in the PPS system and make payment add-ons to address the disparity between the cost of providing medically complex services and the reimbursement Medicare currently provides.

Third, and to a certain extent also addressed by S. 1500, is the fact that HCFA and Congress should replace the current inflation rate update factor for SNFs with a more accurate measurement of the cost of services they are required to provide. This current market basket grossly understates the actual market conditions for SNFs because it understates the annual change in the costs of providing an appropriate mix of goods and services produced by SNFs. SNFs have dramatically changed the services we provide and the acuity levels of the patients we care for. S. 1500 would restore to the SNF market basket the one percent that BBA cut in 1996 through 1998. This would serve as an inflation catch up for SNFs. The minus one-percent *would* continue through 2001.

Fourth and finally, PPS rates are based on cost reports that date all the way back to 1995. We believe providers should have the option of maintaining the current blended rate for the second year of the PPS transition—currently 75% facility-specific/25% federal—or elect to move to the full federal rate immediately. This would prevent facilities that changed the type and volume of Medicare services after 1995—the PPS base year—from being disadvantaged by the transition rate. Again, this is a matter of equity, and a means of easing the transition to PPS. We believe this can be done administratively by HCFA, however HCFA's intransigence requires Congress to act.

Mr. Chairman, as I conclude my remarks, I would like to convey to the Committee that we know the constraints that exist. That is why we've worked so hard to put forward solutions that are realistic, reasonable, responsible and within reach. Each of the actions we recommend would restore funding that would ensure continued quality and access to care for Medicare beneficiaries. And that is why each of the actions we recommend should be adopted for the sake of the patients entrusted to our care. These solutions can only be achieved in a bipartisan fashion, and we look to your leadership. Our nation's seniors expect and deserve no less.

Mr. Chairman and Members of the Committee, I thank you for the opportunity to be here today. On behalf of AHCA, I want to make clear our commitment to providing high quality care to America's frail and elderly. The situation is critical, but it will get worse unless Congress and the Administration work with providers to fix the system.

Mr. BILIRAKIS. Thank you, Miss Rapp.
Miss Roberts, please.

STATEMENT OF NANCY ROBERTS

Ms. ROBERTS. Thank you. My name is Nancy Roberts and I am the chief executive officer of Care New England Home Health. Care New England Home Health Division consists of two home health providers, Kent County Visiting Nurse Association and Kent Hospital Home Care. Both organizations are Joint Commission-accredited, not-for-profit, Medicare-certified agencies located in Rhode Island. The agencies were officially linked in June of last year when the VNA joined Care New England Health System. Last year collectively the organizations provided visits to nearly 10,000 patients.

Mr. Chairman and members of the subcommittee, I am pleased to be here today to present testimony on behalf of the Visiting Nurse Association of America and the National Association for Home Care. We are grateful for your holding these hearings and considering changes to the Balanced Budget Act of 1997 that would stop the hemorrhaging of responsible home health providers and the consequent adverse effects on patients.

The intent of Congress when it passed the Medicare home health provision in the Balanced Budget Act was to decrease rising utilization and reduce the associated expenditure. The leadership and members of VNAA and NAHC both agree that the policy changes were in order. However, we believe that the steps taken by the BBA have inadvertently penalized cost-efficient home health agencies and the patients they serve.

According to HCFA's report in August 1999, nearly 25 percent of all home care agencies in this Nation have closed since the balanced budget passed. The experience in Rhode Island is similar, where 20 percent of the Medicare certified agencies have closed or dropped out of the Medicare program. Nationally, 15 percent fewer Medicare beneficiaries are receiving home health care services. The reduction in Rhode Island is even greater, where 22 percent fewer Medicare beneficiaries are receiving care.

To investigate the effect of the balanced budget on Medicare home health beneficiaries, Congress sought the input of both the GAO and MedPAC. In their reports to Congress in 1999, both confirm that beneficiaries who are most costly to treat are those at risk of losing access to home health care.

MedPAC found that nearly 40 percent of the agencies surveyed responded that because of IPS, they no longer admit all the Medicare patients who they previously would have admitted. Thirty per-

cent of the agencies reported discharging certain Medicare patients because of IPS.

While neither report concluded that access to home health care had become a crisis, I would note that the reports were based on data from the first quarter of 1998.

A recent study conducted by VNAA of its member agencies paralleled MedPAC's findings. While VNAs have historically made every attempt to admit all eligible beneficiaries regardless of condition or ability to pay, many VNAs are now selectively admitting patients or must discharge patients earlier than the optimal time. Many VNAs have made the decision, a difficult decision, to discontinue their participation in the Medicare program, limit specialty programs or eliminate rural service areas.

The VNA and the home care department that I represent has managed to survive these turbulent times, but just barely. We have reduced our costs by 25 percent. In order to achieve this level of reduction, clinical and administrative staff were cut, staff benefits and salaries were reduced, and some programs and patient services were eliminated.

Despite these very, very deep cuts, the two organizations still lost over \$1 million in fiscal year 1998. That represented 17 percent of the total budget. For these two not-for-profit organizations that depend and rely on charitable contributions, this loss was significant and had direct negative impact on our communities and the patients we serve.

As the number of home care providers diminishes, the access problem is exaggerated. It is not uncommon for a hospital discharge planner to call as many as a half a dozen home care providers in search of someone willing to take a patient. Under IPS, agencies are staffing, and I will put in quotes, "just right." You may be familiar with the just-in-time method of inventory management. This is a tool where an organization wants to reliably get products in their plants just before the customer needs them in order to save inventory carrying costs. Well, to some degree home health agencies are being forced to employ just-in-time, just-right staffing.

Because we are forced to employ this kind of method, just-right, just-in-time, there are many days when we have limited staff capacity and have difficulty responding to the unexpected increases in services. Unfortunately, that leaves many patients underserved due to limited staffing ability, waiting for services that they desperately need.

Mr. BILIRAKIS. Please summarize, Miss Roberts.

Ms. ROBERTS. To help solve this dilemma, we find hospital discharge planners looking at reserving slots, scheduling patients in advance. Agencies establish cancellation lists.

So when I hear that there is not an access problem, I have to wonder. I think it is easy to see that the real victims in this situation are our patients and the communities that they serve.

In conclusion, I would offer the following recommendations on behalf of the Visiting Nurse Association and NAHC.

First, to eliminate the scheduled 15 percent additional cut scheduled for October 1, 2000. Second, target specific resources through some sort of an outlier provision to high-cost, high-need patients

to ensure that these eligible beneficiaries have access to needed home care services.

Third, increase the IPS per-visit cost limit. And finally, provide relief from financially disabling overpayment.

I thank you for this opportunity to offer this testimony.

[The prepared statement of Nancy Roberts follows:]

PREPARED STATEMENT OF NANCY ROBERTS, PRESIDENT AND CEO, KENT COUNTY VISITING NURSE ASSOCIATION ON BEHALF OF THE VISITING NURSE ASSOCIATIONS OF AMERICA AND THE NATIONAL ASSOCIATION FOR HOME CARE

Introduction

Mr. Chairman and Members of the Subcommittee: My name is Nancy Roberts, and I am President and Chief Executive Officer of the Kent County Visiting Nurse Association (VNA), which is located in Warwick, Rhode Island.

On behalf of the Visiting Nurse Associations of America (VNAA) and the National Association for Home Care (NAHC), I respectfully submit the following joint comments and recommendations for the public record.

The Kent County VNA is an accredited, Medicarecertified, communitybased home health and hospice agency, which was founded in 1908. Our staff of 175 consists of registered nurses; physical, occupational and speech therapists; home care aides; medical social workers; and clergy and volunteers. We often serve the most costly and chronically-ill patients in our community, regardless of their ability to pay. In 1998, we visited over 6,000 patients.

Mr. Chairman and Members of the Subcommittee, the Kent County VNA is committed to providing quality home health care to all patients in the communities we serve. However, I am deeply concerned that the changes to the Medicare home health program made by the Balanced Budget Act of 1997 (BBA '97) threaten the viability of my agency and the cost-efficient health care that we provide in our communities. I am grateful to you for your leadership in holding this hearing and for your consideration of legislation that would stop the hemorrhaging of responsible providers from the Medicare home health program and the consequent, adverse effect on patients.

The following data illustrate the dramatic changes that have occurred to the Medicare home health program since the passage of BBA'97:

- According to HCFA data from its OSCAR files, as of August 18, 1999, there have been 2486 home health agency closures, nearly 25% of all home health agencies in the United States.
- Approximately 545,270 fewer Medicare beneficiaries received home health services in 1998 than in 1996. The change represents a 15.2% reduction in patients served.
- Home health reimbursement has decreased 29% since 1996.
- Medicare home health spending is now projected by the Congressional Budget Office (CBO) to be reduced by \$48 billion over five years (FY 1998 2002), rather than by \$16.1 billion as initially projected at the time BBA'97 was passed.
- In 1997, home health care represented only 9% of Medicare but was slated for about 14% of the reductions in Medicare spending. Currently, the home health program comprises less than 7% of the Medicare program and is now projected to absorb 24% of the Medicare cuts between FY 1998-2002.

What do these numbers mean in terms of beneficiaries' access to home health care?

Congress passed the BBA'97 Medicare home health provisions to control expenditures and utilization. VNAA and NAHC agree that policy changes were in order; however, we believe that the steps taken by BBA'97 inadvertently penalized cost-efficient home health agencies and patients.

To investigate the effect of BBA'97 on Medicare home health beneficiaries, Congress sought the input of both the General Accounting Office (GAO) and the Medicare Payment Advisory Commission (MedPAC). In their 1999 reports to Congress, both the GAO and MedPAC confirm that the beneficiaries who are most costly to treat are at risk of losing access to home health care. While neither report concluded that access to home health care has become a crisis, it must be noted that the reports are based, for the most part, on data from the first quarter of calendar year 1998.

MedPAC found that, "Nearly 40 percent of agencies surveyed responded that because of the IPS, they no longer admit all Medicare patients whom they would have

admitted previously, and about 30 percent of agencies reported discharging certain Medicare patients because of the IPS." Discharged patients were primarily those with chronic care needs who required a large number of visits and were expensive to serve.

In its June 1999 report, MedPAC states, "The case-mix adjusted PPS [prospective payment system] being developed will not take effect before October 2000. In the meantime, an exclusion policy for very expensive patients could be implemented." The Commission suggests allowing agencies to exclude a small portion of their patients from the aggregate per-beneficiary payment limits to ensure that these beneficiaries will have access to needed services.

Two alarming outcomes of the IPS were revealed in a recent survey by VNAA of its members. While VNAs have historically made every attempt to admit all eligible beneficiaries regardless of condition or ability to pay, many VNAs are now selectively admitting patients or must discharge patients earlier than the optimal time for discharge. Many of the VNAs that responded to the survey made the difficult decision to discontinue participation in the Medicare program or eliminate rural service areas.

Recommendations:

VNAA and NAHC understand the need for Congress to make prudent decisions with respect to changes in the Medicare program. We also believe that the highest priority must be to target resources to ensure that beneficiary access is protected, and that the vital home health infrastructure be stabilized so that it is positioned to respond to future needs of the disabled and elderly. For this reason, we have put a high priority on legislation that would:

1. Eliminate the 15% additional cut scheduled for October 1, 2000;
2. Target specific resources through some type of outlier provision to high-cost, heavy needs patients to ensure that eligible beneficiaries maintain access to needed home health services;
3. Increase the IPS per-visit cost limit; and
4. Provide relief from financially disabling overpayments.

These proposals are in keeping with the concerns that the GAO and MedPAC have outlined and that led members of this Subcommittee and others in the House and Senate to reexamine the home health program changes. The following information provides more detail and rationale for each of these recommendations.

Recommendation #1: Eliminate the 15% payment cut, which is scheduled for October 1, 2000.

Under the BBA'97, expenditures under a PPS were to be equal to an amount that would be reimbursed if the cost limits and per beneficiary limits were reduced 15%. Even if PPS was not ready to be implemented on October 1, 1999, the Secretary of Health and Human Services was required to reduce the cost limits and per beneficiary limits in effect on September 30, 1999, by 15%. The Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA) delayed the 15% reduction for all home health agencies until October 1, 2000.

Congress, HCFA, and home health care providers have looked to PPS as a possible escape from the draconian changes imposed through IPS. However, the method for calculating PPS rates requires HCFA to set payment at levels that will lead to total home health expenditures that are 15% less than under IPS. This means that the PPS payment rates would exacerbate the growing access problems of today.

NAHC and VNAA believe that the 15% expenditure cut to Medicare home health outlays on October 1, 2000, would close down a substantial percentage of home health agencies that have so far survived the IPS. HCFA's August 5 regulation on the new home health cost limits predicts that 93.5% of surviving home health agencies will exceed their FY 2000 per-beneficiary cost limit or per-visit cost limit. In addition, the average agency will have to repay HCFA 12% of its Medicare costs.

Home health providers—who have already experienced an average 29% reduction in reimbursement since the BBA'97 (even with the passage of OCESAA)—are struggling to keep costs under the per-visit and per-beneficiary cost limits and repay IPS-related overpayments. With an additional 15% cut, beneficiaries in many areas of the country would lose access to home health services, and for beneficiaries in many rural counties, this loss would be the loss of any type of local health care.

The 15% expenditure cut is not needed to meet BBA'97 savings goals; CBO estimates that reductions in home care through 2002 will exceed BBA '97 goals by \$32 billion.

Recommendation #2: Target specific resources through some type of outlier provision to high-cost, heavy needs patients to ensure that eligible beneficiaries maintain access to needed home health services.

In addition to the 1999 GAO and MedPAC reports on beneficiary access, a 1998 study conducted by The Lewin Group entitled "Implications of the Medicare Home Health Interim Payment System (IPS) of the 1997 Balanced Budget Act," and a 1998 study by the Center for Health Policy Research of the George Washington University entitled "Medicare Home Health Services: An Analysis of the Implications of the Balanced Budget Act of 1997 for Access and Quality," both found that IPS curtails access to covered services for the sickest, most frail Medicare patients.

The IPS aggregate per-beneficiary limits, based on 1993/94 data, clearly do not reflect the increase in severity of most home health agencies' case-mix populations since that base period. In addition, technological advances in recent years have vastly expanded the scope of services that can be provided to Medicare beneficiaries in their homes. Services such as parenteral and enteral nutrition, chemotherapy and care of ventilator/trach-dependent patients, which used to be provided only on an inpatient basis, can now be provided in the home, thus reducing the need for more costly hospitalization. These services are costly for the home health agency to provide. These services often require nursing staff who have had additional training in administration of drugs and procedures, as well as patient monitoring. In addition, such services require prolonged visits in the patients' homes, as well as high stand-by costs, extensive case management, transition discharge planning and other activities that add further to the cost per visit.

Through an outlier payment, additional resources can be targeted to those providers that care for the high cost patient. An expenditure limit on outlier payments ensures fiscal soundness.

Recommendation #3: Increase the IPS per-visit cost limit.

BBA'97 reduced the per visit cost limits from 112% of the mean to 105% of the median per visit costs for free-standing agencies. IPS forces providers to reduce the total number of visits delivered by patients. However, as the number of visits decreases, costs per visit go up. Under the 1998 OCESAA, the per visit limits were raised from 105% to 106% of the median. This 1% increase was insufficient to help HHAs who are operating under cost limits that have been reduced from 14-22% under BBA'97. The current cost limits are inadequate to cover the costs of providing care and to account for the increased administrative costs of participation in the Medicare program due to HCFA's regulatory initiatives. Agencies in rural areas and inner cities have been particularly hard hit by reductions. Their costs tend to exceed national averages because of longer travel times between visits, higher wages resulting from the lingering personnel shortages in rural areas, or security escorts and language translators in the cities.

Recommendation #4: Provide relief from financially disabling.

BBA '97 did not require HCFA to publish information on calculating the per visit limits until January 1, 1998, even though the limits went into effect beginning October 1, 1997. Likewise, HCFA was not required to publish information related to calculation of agencies' annual aggregate per beneficiary limits until April 1, 1998, despite an October 1, 1997, start date. More than a year after IPS began, many agencies had not yet received notice from their fiscal intermediaries (FIs) providing the visit and per beneficiary limits under which they were expected to operate.

The BBA '97 home health reductions were so deep and occurred so quickly that many agencies were not able to adjust to avoid overpayments. More importantly, overpayments developed because most agencies continued to provide medically necessary health care within the scope of the Medicare benefit rather than terminate care to patients.

These overpayments are not the result of abuse or inefficiency. Rather, most overpayments have occurred because HHAs continue to serve high-cost patients within the scope of Medicare coverage and the payments have already been used to provide legitimate needed care to eligible beneficiaries. Without some relief from these overpayments, it can be expected that agency closures, and the attendant access problems, will accelerate.

Overpayment Relief

HCFA maintains the authority to grant extended repayment plans to any provider receiving an overpayment from the Medicare program. However, the current state of determinations regarding eligibility for extended repayment plans is rife with inconsistency, subjectivity, and confusion. Recently, HCFA communicated to the Congress and the public that it had modified the extended repayment plan process to

authorize automatic approval of three-year repayment plans. In fact, home health agencies have had great difficulty securing even 12-month repayment plans, let alone the newly authorized three-year repayment schedule. Further, the claimed interest free nature of the repayment plans has proven illusory as it has been afforded only to those few home health agencies where the overpayment has been determined prior to filing of the annual cost report. We ask the Subcommittee to ensure that HCFA immediately issue clarifying standards which specifically authorize automatic three-year repayment plans for all types of IPS-related overpayments and that repayment plans be made available on an interest free basis to the extent allowable under current law.

Overpayment Compromises

HCFA has the authority to compromise the collection of Medicare overpayments. At no time in the Medicare program has there been a more appropriate circumstance for exercise of this compromise authority.

HCFA has chosen not to process overpayment compromise requests at this point. The delay in processing these requests virtually guarantees that the requesting home health agency will be at high risk of closure. The Subcommittee should strongly recommend that HCFA utilize its overpayment compromise authority on an expedited basis in order to resolve the inequities created through the implementation of the IPS.

15-Minute Increment Reporting

BBA97 required that claims for home health services on or after July 1, 1999, must contain a code that identifies the length of time for each service visit, measured in 15-minute increments. HCFA issued instructions to the FIs on February 18, 1999, directing them to initiate necessary steps to implement this new billing requirement for all HHAs participating in the Medicare/Medicaid programs (Transmittal No. A-99). HCFA has allowed for a grace period for compliance until September 30, 1997.

This new administrative burden imposes a complex time-keeping requirement for agencies to stop the in-home clock when an interruption in active treatment occurs. The HCFA transmittal defines the "time of service visit" to begin at the beneficiary's place of residence, when delivery of services has actively begun. Agencies must count the number of 15-minute intervals.

The time counted must be actual treatment time. However, in-home time represents only a portion of the total time invested by an agency in caring for a patient. Numerous activities required by the Medicare Home Health Conditions of Participation and needed to ensure effective patient care are often times performed outside the home, including communication with physicians and family members, coordination of services with other home health personnel and community agencies, care planning, and clinical documentation. In order for home care treatment time to be meaningfully quantified, visit time must be better defined and recognized as only part of the resource cost involved in providing home care services.

Neither Congress nor HCFA has indicated how this information will be used. Its value is questionable in light of the ongoing move from a per-visit reimbursement system to prospectively set per-episode payments that are not tied to number of visits or visit length. In light of the substantial financial and administrative strains already being experienced by agencies, we urge you to revisit this requirement.

Thank you again, Mr. Chairman, for the opportunity to present our views. In closing, we urge the Subcommittee to recognize the seriousness of the situation and pass legislation this year. Last year's provisions that were included in OCESAA were helpful in that the 15% cut was delayed for one year, the periodic interim payment (PIP) program was extended until October 1, 2000, and the cost limits received minor adjustments. However, we are now faced with the identical situation of having to face a 15% cut in reimbursement and a discontinuation of PIP one year from now. The cost limits are still severely low and do not enable the majority of agencies that have survived the IPS to care for the most chronically-ill patients. You and the Subcommittee have our gratitude for bringing home health issues to this level of consideration. We look forward to working closely with you to resolve these issues.

HOME HEALTH AGENCY CLOSURES

10/1/97 through 8/18/99

Health Care Financing Administration

Online Survey Certification and Reporting (OSCAR) Data

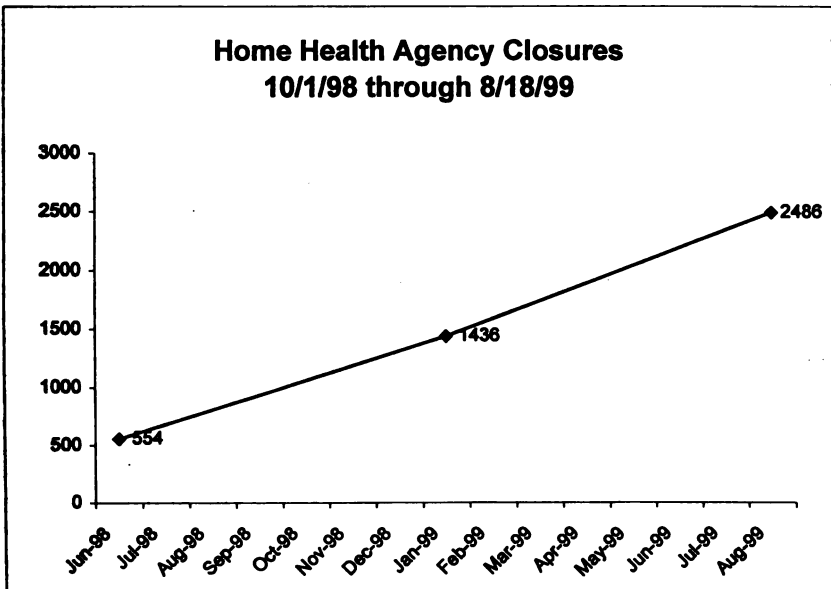
STATE	6/30/98*	1/1/99**	8/18/99
AL	0	2	11
AK	7	9	9
AZ	13	22	45
AR	2	11	13
CA	74	165	232
CO	21	34	24
CT	7	17	22
DE	2	3	5
DC	1	1	1
FL	20	17	30
GA	0	0	3
HI	3	7	3
ID	4	16	17
IL	17	30	71
IN	11	49	80
IA	5	15	25
KS	16	34	46
KY	3	7	5
LA	37	112	200
ME	2	5	12
MD	3	3	10
MA	7	15	15
MI	3	11	27
MN	2	5	10
MS	1	1	5
Mt	20	23	23
MT	0	4	8
NE	1	2	15
NV	8	14	15
NH	1	3	5
NJ	0	3	4
NM	1	5	10
NY	1	5	7
NC	5	7	14
ND	1	1	2
RI	2	2	5
OK	36	90	163
OR	5	1	17
PA	4	22	48
SD	3	5	6

STATE	6/30/98*	1/1/99**	8/18/99
SC	1	5	7
UT	12	19	33
VA	8	15	43
WV	3	4	12
WY	5	9	17
TOTAL	554	1436	2486

*As reported by the General Accounting Office, September 1998 (GAO/HEHS-98-238)

**As reported by the General Accounting Office, May 1999 (GAO/HEHS-99-120)

Home health agency closures continue to accelerate since the implementation of the interim payment system (IPS) on October 1, 1997



Mr. BILIRAKIS. Thank you very much, Miss Roberts.
Dr. Corlin.

STATEMENT OF RICHARD F. CORLIN

Mr. CORLIN. Thank you very much, Mr. Chairman. My name is Richard Corlin. I am a gastroenterologist in private practice in Santa Monica, California and I am also speaker of the AMA's House of Delegates. We appreciate the opportunity to provide the subcommittee with our views on the needed improvements to the Medicare sustainable growth rate system, the SGR.

The SGR, enacted under the Balanced Budget Act of 1997, is a target rate of spending growth for physicians' services. It is calculated each year on the basis of four factors: medical inflation, changes in Medicare fee-for-service enrollment, GDP growth per capita, and changes in spending due to law and regulation.

There are serious problems with the SGR and MedPAC has recommended four areas of improvement. We urge Congress to enact these SGR refinement into law this year.

The four improvements needed are, No. 1, there must be a requirement to correct HCFA's projection errors and restore the \$3 billion SGR shortfall resulting from these errors. No. 2, the SGR must be increased to account for physician costs due to adoption of new technologies.

No. 3, measures must be implemented to curtail volatility in physician payment rate and avoid steep cuts in the future. And No. 4, HCFA and MedPAC must be required to provide information and data on payment updates.

Our testimony today will focus primarily on two of these four needed SGR refinements: HCFA's projection errors and the need to increase the target above GDR growth.

HCFA must correct the projection errors in the 1998 and 1999 SGR and should be required to correct projection errors each year as actual data becomes available. Our view is totally in accord with MedPAC's recommendation. We recognize that HCFA has to use estimates to calculate the SGR for the coming year and as a result, physician payment updates are not based on actual data but on projected data, which has so far proven to be erroneous.

In the first 2 years of the SGR, erroneous HCFA projections have already short-changed physician payments by more than \$3 billion. For example, in establishing the 1999 SGR, HCFA projected that Medicare managed care enrollment would rise by 29 percent in 1999. This error led to a projected drop in fee-for-service enrollment and a negative 1999 SGR. Data now shows that managed care enrollment has increased only by 11 percent and this means that physicians are caring for over 1 million more patients in the Medicare fee-for-service system than are accounted for by the SGR statement by HCFA.

The earlier statements, with all due respect, made by HCFA that they have the ability to erroneously make an estimate but do not have the legal right to correct their own estimates are simply beyond the limits of credulity. I might point out, Mr. Chairman, that the highest amount of shortfall in any State was to the State of Florida, whose beneficiaries' physicians had a shortfall of \$285 million.

In addition, the SGR needs to be set at GDP plus 2 percentage points, the way it was originally intended to take into account two main factors responsible for increasing health care costs: advances in technology and an aging population.

Under the Balanced Budget Act of 1997, the SGR limits growth in the use of health care services by the elderly and disabled patients to the rate of growth of the GDP. We know and CBO forecasts confirm that GDP growth in the next decade will lag behind growth in patient needs for health care services. Thus, no matter how cost-effective physicians are in our care for our beneficiaries, Medicare physician payment rates are virtually guaranteed to decline unless these corrections are made.

MedPAC has recommended that the SGR include a factor higher than GDP to account for, and I quote, "cost increases due to improvements in medical capability and advances in scientific technology." We strongly agree with MedPAC.

We also urge Congress to consider a long-term approach to setting an appropriate growth target. For instance, Congress could require the Agency for Health Care Policy and Research to study the impact on utilization of No. 1, advances in technology, No. 2, aging and other changes in the characteristics of Medicare enrollees, and three, shifts in sites of service and a report be made on this study to MedPAC.

Other serious problems with the SGR must also be addressed and they are explained in our written testimony.

Physicians, regardless of our specialty, are unanimous in our concern that payment cuts due to flaws in the SGR, on top of more than a decade of previous cuts, could threaten our ability to continue to offer our Medicare patients the finest medical care in the world. Thus the SGR system must be fixed and it must be fixed this year. Thank you, and I yield the balance of my time.

[The prepared statement of Richard F. Corlin follows:]

PREPARED STATEMENT OF RICHARD F. CORLIN ON BEHALF OF THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association (AMA) appreciates the opportunity to present to this Subcommittee our views concerning improvements to the Medicare sustainable growth rate (SGR) system for physicians' services, and appreciates the Subcommittee's focus on this important issue. As Congress prepares to consider Balanced Budget Act (BBA) refinements and Medicare reforms, the AMA urges inclusion of improvements in Medicare's SGR system in any legislation approved by the Subcommittee.

Enacted under the BBA, the SGR establishes a target growth rate for Medicare spending on physician services, then annually adjusts payments up or down, depending on whether actual spending is below or above the target. The SGR system was intended to slow the projected rate of growth in Medicare expenditures for physicians' services.

Physicians are the only group subject to this target, despite the fact that Medicare spending on physician services has been growing more slowly than other Medicare benefits. Although the BBA included measures to slow projected growth in these other benefits, the Congressional Budget Office continues to forecast much higher average annual growth rates for other services than for physician services over the next decade. In contrast to annual growth in outlays of 4.6 percent for inpatient hospital services, 5.7 percent for skilled nursing facilities, 6.5 percent for home health, and 14.6 percent for Medicare+Choice plans, average annual growth in physician services is projected at only 3.1 percent from 2000-2009.

Physicians were subject to significant and disproportionate Medicare payment cuts prior to the BBA, yet we have never abandoned our elderly and disabled pa-

tients. From 1991-97, physician payment updates already had slipped 10 percent below growth in medical practice costs.

In its March 1999 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) identified serious problems in the SGR system and recommended significant improvements to it. The AMA and the national medical specialty societies share MedPAC's concerns and believe that improving the SGR is a critical component of efforts to ensure that the 85 percent of Medicare beneficiaries who are enrolled in the fee-for-service program continue to receive the benefits to which they are entitled.

Specifically, the physician community is concerned that the growth limits in the current SGR system are so stringent that they will have a chilling effect on the adoption and diffusion of innovations in medical practice and new medical technologies. In addition, we are concerned that the Health Care Financing Administration (HCFA) did not revise the projections it used in the 1998 SGR when data proved HCFA erroneous. Further, HCFA stated it will not correct 1999 SGR errors without a congressional mandate, despite that in the first two years of the SGR, erroneous HCFA estimates have already shortchanged the target by more than \$3 billion. Finally, we are concerned that the SGR could also cause future payments to be highly volatile and fall well behind inflation in practice costs.

MEDICARE PHYSICIAN PAYMENTS AND THE BALANCED BUDGET ACT

Medicare payments for physicians' services are updated annually by HCFA. Payment rates are based on a relative value scale system, enacted under OBRA 89, that reflects the physician work, practice expense and professional liability insurance costs involved in each service. The relative value for each service is multiplied by a dollar conversion factor to establish actual payment amounts. The conversion factor is required to be updated each calendar year, which involves, in part, establishing an update adjustment factor (UAF) that is adjusted annually by the SGR.

MedPAC recommends, and the AMA agrees, that Congress revise the SGR system as follows—

- The SGR should include a factor of growth in real gross domestic product per capita plus an allowance for cost increases due to improvements in medical capabilities and advancements in scientific technology;
- The Secretary should be required to publish an estimate of conversion factor updates by March 31 of the year before their implementation;
- The time lags between SGR measurement periods should be reduced by allowing calculation of the SGR and update adjustment factors on a calendar year basis;
- HCFA should be required to correct the estimates used in the SGR calculations every year; and
- The SGR should reflect changes in the composition of Medicare fee-for-service enrollment.

THE SUSTAINABLE GROWTH RATE SYSTEM

The SGR system was enacted under the BBA and replaces the Medicare Volume Performance Standard system, which had been the basis for setting Medicare conversion factor updates since 1992. The SGR sets a target rate of spending growth based on four factors: changes in payments for physician services before legislative adjustments (essentially inflation); changes in Medicare fee-for-service enrollment; changes in real per capita gross domestic product (GDP); and an allowance for legislative and regulatory factors affecting physician expenditures. Growth in real per capita GDP represents the formula's allowance for growth in the utilization of physician services.

The target rate of spending growth is calculated each year and is designed to hold annual growth in utilization of services per beneficiary to the same level as annual GDP. Physician payment updates depend on whether utilization growth exceeds or falls short of the target rate. If utilization growth exceeds GDP, then payment updates are less than inflation. If utilization is less than GDP, payment updates are above inflation.

Because of the serious problems with the SGR system, as discussed below, four improvements must be included in legislation to fix the SGR:

- There must be a requirement to correct HCFA's projection errors and to restore the \$3 billion SGR shortfall resulting from these errors;
- The SGR must be increased to account for physician costs due to adoption of new technology;
- Measures must be implemented to curtail volatility in physician payment rates and avoid steep cuts in the future; and

- HCFA and MedPAC must be required to provide information and data on payment updates.

PROBLEMS WITH THE SGR SYSTEM

Of the needed improvements listed above, we wish to focus on two major problems with the SGR. First, there is a "projection error" problem. Specifically, in determining the SGR each year, HCFA must estimate certain factors that are used to calculate the SGR. In the first two years of the SGR system, HCFA has seriously miscalculated these factors, and thus physicians have been shortchanged by several billion dollars. In addition, these projection errors will continue each year, and the resulting shortfalls will be compounded.

The second major problem with the SGR system is that it does not allow growth in physician payments sufficient to account for physicians' costs due to technological innovations.

In addition, as discussed above, there are other problems with the SGR system, which we have separately addressed below.

Unlike some other Medicare payment issues, the problems with the SGR system and their solutions are a matter on which the physician community is unified. National organizations representing diverse medical specialties, including surgeons, primary care physicians and others, as well as organizations representing medical colleges and group practices, have been working closely together with the AMA to address these complex issues. On behalf of the entire physician community, we are asking Congress to take the necessary steps to assure that we can continue to afford to provide our Medicare patients with the best medical care available in the world.

The Projection Error Problem

Two of the four factors used to calculate the SGR target each year are growth in U.S. GDP and fee-for-service enrollment growth. Because the target must be calculated before the year begins, HCFA can only speculate as to what GDP growth will be and how many people will enroll in fee-for-service versus managed care. Recognizing the need for such speculation, HCFA acknowledged in a 1997 physician rate update regulatory notice that the actual data for each year, once available, might reveal errors in its estimates of as much as 1 percent, or \$400 million. HCFA also promised that the difference between its projections and actual data would be corrected in future years.

In the first two years of the SGR, erroneous HCFA estimates have already shortchanged physician payments by more than \$3 billion. These projection errors have not been corrected and HCFA does not plan to do so. Specifically, one year after the 1997 notice, HCFA reneged on its pledge to correct SGR errors and simultaneously issued its most egregious error, projecting Medicare managed care enrollment would rise 29 percent in 1999, despite the many HMOs abandoning Medicare in 1999. This error led, in turn, to a projected drop in fee-for-service enrollment and a *negative* 1999 SGR. Data now show that managed care enrollment has increased only 11 percent, a fraction of HCFA's projection, which means *physicians are caring for 1 million more patients in Medicare fee-for-service than were forecast*.

The 1998 and 1999 SGR projection errors are a serious problem. The SGR is a cumulative (as opposed to an annual) system, and the cumulative SGR target is like a savings account for physician services. As discussed, HCFA's errors have left a \$3 billion shortfall in this account, which, if not restored, will either produce unwarranted payment cuts or deficient payment increases. Although the President's 2000 budget proposes to address the projection errors, we are concerned that HCFA may correct the errors in a way that will effectively cancel any benefit to payment rates from using accurate data.

Physicians have faced a decade of payment cuts without ever abandoning Medicare patients. We have done our part to keep costs within the limits imposed by the BBA. Now, Congress must do its part by insisting that payment updates be based on correct SGR estimates.

The SGR Must Allow for Technological Innovations and Other Factors Impacting Utilization of Health Care Services

MedPAC has also recommended that Congress revise the SGR to include a factor of growth in real gross domestic product per capita plus an allowance for cost increases due to improvements in medical capabilities and advancements in scientific technology.

The system is currently designed to hold annual utilization growth at or below annual GDP growth. A common method for policymakers to evaluate trends in national health expenditures is to look at growth in health spending as a percentage of GDP, but this approach is replete with problems. There is no true relationship

between GDP growth and health care needs. Forecasts by Congressional Budget Office and the U.S. Census Bureau indicate that real per capita GDP growth will average about 1.5 percent per year over the next decade. This is far below historical rates of Medicare utilization growth. Indeed, at 5.9 percent, average annual per beneficiary growth in utilization of physicians' services was three to four times higher than GDP growth from 1981-1996. Thus, if history is any guide, holding utilization growth to the level of GDP growth virtually guarantees that Medicare physician payments will decline.

A primary reason for this lack of congruity between GDP and Medicare utilization is that GDP does not take into account health status trends nor site-of-service changes. Thus, if there were an economic downturn with negative GDP growth at the same time that a serious health threat struck a large proportion of Medicare beneficiaries, the consequences could be disastrous.

Secondly, GDP does not take into account technological innovations. The only way for technological innovations in medical care to really take root and improve standards of care is for physicians to invest in those technologies and incorporate them into their regular clinical practice. The invention of a new medical device cannot, in and of itself, improve health care—physicians must take the time to learn about the equipment, practice using it, train their staff, integrate it into their diagnosis and treatment plans and invest significant capital in it. Yet physician spending is the only sector of Medicare that is held to as stringent a growth standard as GDP and that faces a real possibility of payment cuts of as much as 5 percent each year. Keeping utilization growth at GDP growth will hold total spending growth for physician services well below that of the total Medicare program and other service providers.

To address this problem, as recommended by MedPAC, the factor of growth under the SGR relating to GDP must be adjusted to allow for innovation in medical technology. We believe to implement adequately MedPAC's recommendation, the SGR should be set at GDP + 2 percentage points to take into account technological innovation, as discussed further below.

In addition, we urge that Congress consider a long-term approach to setting an appropriate growth target that takes into account site-of-service changes, as well as health status and other differences between Medicare's fee-for-service and managed care populations that lead to differential utilization growth. Thus, we believe that the Agency for Health Care Policy and Research (AHCPR) should be directed to analyze and provide a report to MedPAC on one or more methods for accurately estimating the economic impact on Medicare expenditures for physician services resulting from improvements in medical capabilities and advancements in scientific technology, changes in the composition of enrollment of beneficiaries under the fee-for-service Medicare program and shifts in usage of sites-of-service.

Technological Innovation

Congress has demonstrated its interest in fostering advances in medical technology and making these advances available to Medicare beneficiaries through FDA modernization, increases in the National Institutes of Health budget, and efforts to improve Medicare's coverage policy decision process. The benefits of these efforts could be seriously undermined if physicians face disincentives to invest in new medical technologies as a result of inadequate expenditure targets.

As first envisioned by the PPRC, the SGR included a 1 to 2 percentage point add-on to GDP for changes in medical technology. Ever-improving diagnostic tools such as magnetic resonance imaging, new surgical techniques including laparoscopy and other minimally-invasive approaches, and new medical treatments have undoubtedly contributed to growth in utilization of physician services and the well-being of Medicare beneficiaries. For example, a recent paper published by the National Academy of Sciences indicated that from 1982-1994 the rates of chronic disability among the elderly declined 1.5 percent annually.

With GDP projected to grow by 1.5 percent annually, the failure to allow an additional 1 to 2 percentage points to the SGR for technological innovation means that the utilization target is only half the rate that was originally planned. Technological change in medicine shows no sign of abating, and the SGR should include a technology add-on to assure Medicare beneficiaries continued access to mainstream, state-of-the art quality medical care.

Site-of-Service Shifts

Another concern that should be taken into account by the GDP growth factor is the effect of the shift in care from hospital inpatient settings to outpatient sites. As MedPAC has pointed out, hospitals have reduced the cost of inpatient care by reducing lengths-of-stay and staff and moving more services to outpatient sites, including

physician offices. These declines in inpatient costs, however, are *partially* offset by increased costs in physician offices. Thus, an add-on to the SGR target is needed to allow for this trend.

Beneficiary Characteristics

The SGR should also be adjusted for changes over time in the characteristics of patients enrolling the fee-for-service program. A MedPAC analysis has shown that the fee-for-service population is older, with proportions in the oldest age groups (aged 75 to 84 and those age 85 and over) increasing, while proportions in the younger age group (aged 65-74) has decreased as a percent of total fee-for-service enrollment. Older beneficiaries likely require increased health care services, and in fact MedPAC reported a correlation between the foregoing change in composition of fee-for-service enrollment and increased spending on physician services. If those requiring a greater intensity of service remain in fee-for-service, the SGR utilization standard should be adjusted accordingly.

Other Problems with the SGR System

Stabilizing Payment Updates under the SGR System

The AMA strongly agrees with MedPAC's further recommendation that Congress should stabilize the SGR system by calculating the SGR and the update adjustment factor on a calendar year basis.

Instability in annual payment updates to physicians is another serious problem under the SGR system, as has been acknowledged by HCFA. Projections by the AMA, MedPAC and HCFA show the SGR formula producing alternating periods of maximum and minimum payment updates, from inflation plus 3 percent to inflation minus 7 percent. Assuming a constant inflation rate, these alternating periods could produce payment decreases of 5 percent or more for several consecutive years, followed by increases of similar magnitude for several years, only to shift back again. These projections are based on constant rates of inflation (2 percent), enrollment changes, GDP growth and utilization growth. There is a serious problem when constant, stable rates of change in the factors driving the targets lead to extreme volatility in payments that are entirely formula-driven.

A primary reason for this instability is the fact that there is a time lag in measurement periods for the SGR. Specifically, while physician payment updates are established on a calendar year basis, SGR targets are established on a federal fiscal year basis (October 1 through September 30) and cumulative spending (used to calculate the SGR) is established on an April 1 through March 31 basis. These time periods must all be consistent and calculated on a calendar year basis to attempt to restore some modicum of stability to the SGR system.

Simulations by the AMA and MedPAC have also shown, however, that the change to a calendar year system will not, by itself, solve the instability problem. Additional steps would be needed. The wide range of updates that are possible under the current system, from inflation + 3 percent to "7 percent, is one reason for the instability. The lower limit is also unacceptably low, and, assuming an MEI of 2 percent, represents an actual 5 percent cut in the conversion factor in a single year. These levels of payment cuts would be highly disruptive to the market, and likely would have the "domino effect" of impacting the entire industry, not simply Medicare fee-for-service. Many managed care plans, including Medicare+Choice and state Medicaid plans, tie their physician payment updates to Medicare's rates. Thus, payment limits under current law must be modified to assist in stabilizing the SGR system. We recommend that the current limits on physician payment updates (MEI +3 percent to MEI -7 percent) be replaced with new, narrower limits set at MEI +2 percent and MEI -2 percent.

Finally, use of the GDP itself also contributes to the instability of the payment updates since GDP growth fluctuates from year to year. Thus, we recommend measuring GDP growth on the basis of a rolling 5-year average.

Payment Preview Reports

Finally, MedPAC has also recommended that Congress should require the Secretary of the Department of Health and Human Services to publish an estimate of conversion factor updates prior to the year of implementation. We agree.

When the SGR system was enacted to replace the previous Medicare Volume Performance Standards, the requirements for annual payment review reports from HCFA and the PPRC were eliminated along with the old system. Without these reports, it is impossible to predict what the payment update is likely to be in the coming year, and it is impossible for Congress to anticipate and respond to any potential problems that may ensue from an inappropriate update or a severe projection error.

Changes in Medicare physician payment levels have consequences for access to and utilization of services, as well as physician practice management. These consequences are of sufficient importance that the system for determining Medicare fee-for-service payment levels should not be left unattended on a kind of "cruise control" status, with no "brake" mechanism available to avoid a collision.

The AMA, therefore, urges that the payment preview reports be reinstated. Specifically, we believe that HCFA should be required to provide to MedPAC, Congress and organizations representing physicians quarterly physician expenditure data and an estimate each spring of the next year's payment update. MedPAC could then review and analyze the expenditure data and update preview, and make recommendations to Congress, as appropriate.

CONCLUSION

Enactment of the SGR system improvements recommended by MedPAC are critical to the continued ability of our nation's physicians to be able to offer our Medicare patients the benefits of the finest medical care available in the world. If these improvements are not put in place, the SGR system could lead to severe payment cuts in the Medicare physician fee schedule and payments for services that do not accurately reflect their costs. The cuts resulting from both the statutory design of the SGR system and administration of the system by HCFA would be in addition to more than a decade of cuts in physician payments. For example, in the six years from 1991-1997, overall Medicare physician payment levels fell 10 percent behind the rate of growth in medical practice costs. Many individual services and procedures faced even deeper cuts.

Recent survey data from the AMA's Socioeconomic Monitoring System indicates that these payment changes are having very significant effects on the practice of medicine. Of 2,450 randomly selected physicians that were surveyed from April-August 1998, 35 percent reported they are not renewing or updating equipment used in their office, are postponing or canceling purchasing equipment for promising new procedures and techniques, or are performing many procedures in hospitals that were formerly performed in the office. Three quarters of these physicians reported that Medicare payment cuts were an important factor in their decisions to defer or cancel these investments in capital.

With these kinds of changes already taking place in response to previous payment changes, we have grave concerns about the effects of the further reductions that could take place due to the SGR or incorrect practice expense values. In order for the medical innovations that will come from Congress' enhanced funding of biomedical research, FDA modernization, and better Medicare coverage policies to translate into ever-improving standards of medical care, physicians must be able to adopt these innovations into their practices. It is already clear that Medicare payment cuts are threatening continued technological advancement in medicine, and this is a threat that affects all of us, not just Medicare beneficiaries. Clearly, reversal of the trend to move services away from inpatient sites into ambulatory settings could also have severe consequences for health care costs, as well as patient care.

We appreciate the efforts of the members of the Subcommittee to explore the problems presented by the SGR system, as well as the opportunity to discuss our views on this extraordinarily important matter. We urge this Subcommittee and Congress to consider MedPAC's recommendations and the recommendations we have discussed today, and are prepared to engage fully in detailed discussions with the Subcommittee and Congress as we work to achieve a workable and reasonable solution.

Mr. BILIRAKIS. Dr. Corlin has testified before.

Mr. Holveck.

STATEMENT OF DAVID P. HOLVECK

Mr. HOLVECK. Thank you, Mr. Chairman and committee members. I will forego a written statement and really take the opportunity, and I value this opportunity on behalf of the Bio Organization, to give a very specific and, I think, pointed comment relative to the proposed changes in the Balanced Budget Act, specifically on ambulatory payment classification.

This particular classification, we believe, is a very simple solution to a very complex problem. I think what we all have realized in the development of new technologies in health care, and specifi-

cally biotechnology, is that these health care solutions are complex. I think we know from just the time it take to develop them, how we study them, the patient populations that we review, we do not do it with 10; we do it with 10,000. I think that should demonstrate the complexity of the human system, the heterogeneity of the system.

For us to propose a policy for ambulatory infusion of therapeutics in a way that really classifies a single payment system for all is akin to giving everyone a size 5 narrow shoe. It does not work. I think you have to reflect on the complexity that we deal with and I think we have to move in a fashion that allows proper reimbursement for infused drugs and not penalize, most importantly, the patients, who are really the beneficiaries of this advanced technology.

Let me give you an example of how a system could evolve. We all have heard today that there are sensitivities to cancer treatment and the proposed changes do recognize various classifications but I still think they are not divided enough to give the full complementary of the various treatments to various cancers. But outside of that, there is no recognition. There is a flat fee, at least being proposed.

Centocor is an example of a company that last year received an approval for a drug for Crohn's disease, a devastating disease that is chronic and generally lasts for life. It is a drug that was the first approved under the Orphan Law and the first one approved in 30 years. The usefulness of this drug compared to the patient stay in the hospital, which generally averaged 8 days a year, \$35,000 a year—surgery could average \$47,000 a year—can be augmented by a \$1,900 infusion.

The flat rate that is being proposed is \$99.24. I doubt seriously that the hospitals are going to eat that charge and what is going to happen is the patients are not going to get the treatment. Alternatively, they could turn to doctors or physicians' offices but they are not facilitated to implement that change.

So I really believe that we are at a point where we have to recognize the complexity. I think we have to realize that you and Congress have primed the pump with FDAMA, with orphaned drug incentives, with NIH funding that has created a high-value technology that needs to now get into the hands of the public and the needed patient.

I guess I would just close by leaving you a little imagery. I think we all see on the 6 news where we find that this Nation is quick to respond to the needs of many nations with national disasters or political upheaval that really disrupt the public quality of life. We load the transport planes. We get the supplies and the needed elements on the tarmac, only to see, in frustration, that we cannot move them off the tarmac because of either political instability or infrastructure.

I think we sit here today and we have primed the pump, we have the needed technology on the tarmac. I challenge you to give us policies that will get it into the hands of the public. Thank you.

[The prepared statement of David P. Holveck follows:]

PREPARED STATEMENT OF DAVID P. HOLVECK ON BEHALF OF THE BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Mr. Chairman, Members of the Committee, thank you for the opportunity to testify today on the need to correct unanticipated consequences of the Balanced Budget Act of 1997.

I am David Holveck, Chief Executive Officer of Centocor, a twenty-year old biopharmaceutical company headquartered in Malvern, Pennsylvania. Centocor is a leading biopharmaceutical company that creates, acquires and markets cost-effective therapies that yield long-term benefits for patients and the healthcare community. Developed through monoclonal antibody technology, Centocor's mission is to help physicians deliver innovative treatments to improve human health and restore patients' quality of life.

This morning I am testifying on behalf of the Biotechnology Industry Organization (BIO), representing over 830 companies, universities, research institutions, state biotechnology centers and affiliates in 46 states.

BIO asked me to testify to highlight a Balanced Budget Act of 1997 issue that has not received much attention. I am here to talk about the devastating impact HCFA's proposed Ambulatory Payment Classification (APC) system would likely have on patients who benefit from biotechnology products and the research that makes new therapies and cures possible. HCFA has not issued the final APC rule to date, so the full impact has not yet been felt. This issue is a sleeping giant.

To illustrate the biotech industry's concern, I will use my company's experience with patients suffering from Crohn's disease, an orphan disease. It is only one example of dozens our industry could present. The APC system, as proposed, will negatively affect patients suffering with cancer and its related side-effects, end-stage renal disease, hemophilia, and a host of orphan diseases.

I would like you to consider two points as you discuss the unanticipated outcomes of the BBA and select which problems merit legislative correction.

1) I am sure Congress' intent was not to establish a hospital outpatient prospective payment system that compromises quality of care and biomedical research, or that limits access to appropriate biologics and pharmaceutical products.

- 2) If all drugs and biologics are bundled into the proposed APC system, it will:
- decrease patient access to current important and often life-saving therapies.
 - create incentives for hospitals to use biotechnology products and drugs in a less efficient manner.
 - encourage the use of the cheapest drug or biologic rather than the most effective one.
 - create a potential shift of patient treatment to less intensive settings, such as physician offices, even when it is not clinically appropriate.
 - significantly decrease incentives to develop new biotechnology products targeted for indications that affect elderly populations.

Congress must get involved to ensure that a HCFA rule based on flawed data and unsound policy is not finalized. It is better to correct this problem before the damage is done.

I. BRIEF BACKGROUND

The Balanced Budget Act of 1997 (BBA) requires HCFA to establish a prospective payment system (PPS) to reimburse for care provided to Medicare beneficiaries in hospital outpatient departments. In addition, the BBA grants the Secretary of Health and Human Services authority to exempt certain products and services from the outpatient prospective payment system (PPS).

Since the passage of BBA, HCFA, in consultation with a private contractor, created a hospital outpatient department bundling system and called each bundle an Ambulatory Payment Classification (APC). The proposed rule to establish 346 of these APCs was published in the Federal Register on September 8, 1998. Due to errors in data used to create some APCs and other delays, the comment period was extended numerous times from its initial end date of July 30, 1999. HCFA received thousands of comments to the proposed rule. As of today's hearing, the agency has not published a final rule, but all indications are that HCFA is unlikely to revise the proposed system in a significant enough way that our concerns would be addressed. Although I hope the agency proves us wrong, Congress must involve itself now to ensure that this proposed bundling system does not go into effect and harm the quality of patient care.

II. THE PROPOSED RULE'S DETRIMENTAL EFFECTS TO PATIENT CARE: TREATMENT OF CROHN'S DISEASE AS ONE EXAMPLE

In 1998, Centocor began marketing Remicade, a breakthrough orphan drug product for Crohn's disease, a chronic inflammatory bowel disease. The symptoms include diarrhea, severe abdominal pain, fever, chills, nausea and fistulae (painful draining of abnormal passages between the bowel and surrounding skin), this is a painful, debilitating disease that until the introduction of Remicade could not be adequately treated without drugs that produce serious side-effects. Remicade was the first treatment specifically designed for Crohn's disease in more than 30 years.

A typical course of therapy for Remicade involves a two-hour infusion administered by a physician once every eight weeks. The infusion time and the potential complications that often come with the disease make the hospital outpatient department a very attractive setting for service. In fact, since its launch last year, 80 percent of the patients receiving Remicade have been treated in the hospital outpatient setting.

A typical course of Remicade therapy costs \$1,900, yet the APC reimbursement as proposed would equal only \$99.24. To a hospital administrator responsible for keeping a hospital solvent, this APC underpayment means a loss of \$1,726.00 for the treatment of one patient per infusion. This loss does not even factor in staff and site of service costs. Since Remicade is infused once every eight weeks, caring for one Crohn's patient would cost the hospital more than \$11,705.00 annually.

Since there is great sensitivity toward drug pricing among members of Congress, let me emphasize that Remicade is a cost-effective product for those with Crohn's disease. Each year, approximately one in five patients with Crohn's disease requires hospitalization. In fiscal year 1995, the mean hospital charge for these patients was \$35,378. The mean length of stay in the hospital was 8.7 days. Of the patients requiring surgery, approximately 57 percent had a mean charge of \$46,354. Common surgical procedures for patients with Crohn's disease include resection of the bowel, draining of abscesses and ileostomies. The use of Remicade can lower the number of hospitalizations as well as the need for expensive surgeries. Using the product also could capture savings by eliminating substantial health-care costs often associated with the long-term side effects of previous therapies used to treat Crohn's disease. There is no accurate way to put a number on improving quality of life; however, it is an important factor to consider. A \$1,900 drug that must be taken every eight weeks may seem expensive, but, in the context of providing patients' treatments to avoid future health care costs and live a more normal life, this is a cost-effective intervention.

III. THE IMPACT THE APC SYSTEM WILL HAVE ON ONE ORPHAN DRUG PRODUCT EXPLAINS THE CONCERNS RAISED BY BIO ON BEHALF OF THE BIOTECH INDUSTRY.

While the above product is only one example, the problems raised apply broadly. Here are our industry's concerns with the APCs as they relate to drugs and biologics.

A. As proposed by HCFA, the APC system could penalize hospitals for providing the most clinically appropriate therapies.

As demonstrated in the Remicade example, the proposed APC system will threaten patients' access to important and often life-saving therapies because it does not allow adequate payment for most biotechnology products and drugs. For a variety of technical reasons involving the inadequacy of the database and its analysis, many biopharmaceuticals were not even included in the APC calculations. For example, HCFA excluded all products that received codes after 1996. A perfect example of this is Remicade. FDA did not approve the drug until 1998, so the cost of Remicade was not factored into any APC. The inherent bias used in selecting claims for analysis, along with the absence of detailed coding data for drugs and biologics means the proposed APC system has no real basis in actual costs or patterns of care for biotechnology products or drugs.

Medicare beneficiaries' access to biotechnology products and drugs should not be determined solely on the cost of a product. Nevertheless, the APC system creates incentives for hospital outpatient departments to make decisions primarily on this basis, potentially, denying Medicare beneficiaries access to high-cost, high-value products. Clearly, this was not the intent of Congress when it mandated a prospective payment system for hospital outpatient department services.

B. Clinicians may not be able to determine the most appropriate setting of care for a given patient without being adversely influenced by inappropriate payment

The APCs as currently described will force a physician to prescribe an inexpensive drug in the hospital outpatient setting or look for an alternative site to administer the optimal therapy. This is because hospitals cannot sustain long-term underpayment and remain solvent. The APC system will create an incentive to shift care to other, potentially less-appropriate settings.

Many patients may lose the option to receive their care in hospital outpatient departments. Physicians will be obligated to treat these patients at alternative sites, whether or not these alternatives are the best settings for the procedure involved. In the case of Remicade, theoretically, it could be clinically appropriate to administer the drug in a physician's office where reimbursement rates would cover the cost of the drug. However, as a practical matter, this option currently does not exist. Gastroenterologists are the specialists who typically treat patients with Crohn's disease. Because few other infused therapies exist for gastroenterological indications, these physicians traditionally do not have the facilities, equipment, and skilled personnel to administer prolonged infusions in the office. In addition, for some patients—typically those with serious complications and co-morbidities or with a history of infusion reactions—it never may be clinically appropriate to receive a prolonged infusion in a physician's office.

C. Many are concerned that the proposed APC system would disproportionately affect access to care in rural areas where hospital outpatient departments are the exclusive providers of technology-based services

Because of the acquisition, storage and processing costs, only providers with substantial operating budgets can supply many biotechnology products and drugs. It simply is not realistic to expect physician offices in rural regions to provide the full range of biotechnology products and drugs currently available in hospital outpatient departments. Beneficiaries who lose access to appropriate outpatient care and subsequently go without therapy may suffer complications or a worsening of the disease that could otherwise have been avoided.

IV. THE PROPOSED APC SYSTEM MAY HAVE A NEGATIVE IMPACT ON DEVELOPMENT OF CRITICAL NEW TECHNOLOGIES AND THERAPIES

As a CEO of a company researching and developing new technologies, I am very concerned with how this new APC system would directly impede the research, development and adoption of new technologies.

Under the proposed rule, a new technology's APC assignment will not reflect its true costs for several years after it is assigned a unique HCFA Common Procedure Coding System (HCPCS) billing code.

First, the technology will be billed with a miscellaneous HCPCS code and will be assigned to the lowest paying APC available.

Then, once a unique HCPCS code is assigned, HCFA proposes to determine which APC includes services that are most similar clinically and with respect to resources to the new technology.

If several APCs are identified, HCFA will assign the new technology to the lowest paying option without adjusting the relative weight or payment amount of the recipient APC.

Finally, only after an additional period of at least two years will the technology be eligible for assignment to the most appropriately paying APC¹. This will make it very difficult for hospitals to offer their patients early access to the breakthrough products because they won't be reimbursed adequately. This will lower the standard of care for Medicare beneficiaries.

The proposed recalibration approach for updating APC weights may not allow hospitals to cover the cost of new technologies for several years. The inequity of purposely assigning new technologies to the lowest paying APCs is compounded by the fact that Medicare proposes to update APC assignments only after two or more years of data collection and only to recalibrate the payment levels of each APC infrequently. The result of HCFA's proposed updating methodology is that an APC that includes a new technology may not be assigned an appropriate weight for more than three years. This delay could have a chilling effect on the evolution of medical care.

The proposed APC system also would create substantial disincentives to private sector development of such products. The development of life-saving therapies de-

¹ The preamble to the proposed rule states that HCFA will not create an APC for an entirely new code, but will assign it to an existing group while accumulating data for at least two years in the APC (63 FR 47579).

depends on the ability of biotechnology companies to achieve a rate of return on their investment of resources commensurate with the risk. Otherwise investors, who supply most of the capital for research and development, will not support biotechnology companies. It takes an average of eight years and more than \$350 million to bring a new drug to market. New biotechnology products and drugs often are breakthrough technologies that offer treatment to patients who have few options. HCFA has not taken this into consideration in developing its APC system. As a result, the proposed APC system is likely to severely underpay for biotech products, thereby significantly decreasing the incentives to develop new medicines targeted for indications that affect the elderly population. This result runs counter to Congress' many other efforts to speed the development of innovative products for the seriously ill, e.g. orphan tax credits, doubling of the NIH budget, and the Food and Drug Administration Modernization Act (FDAMA).

V. CATEGORIES OF THERAPIES AT PARTICULAR RISK OF UNDERPAYMENT AND UNDER-UTILIZATION DUE TO APCs

In an effort to identify which products would be most harmed by the APC system, BIO, in conjunction with the Pharmaceutical Research and Manufacturers Association (PhRMA) identified seven categories in particular jeopardy. Both trade groups urged HCFA to carve out the following:

1. *"New" Drugs and Biological Products.* New technologies are awaiting proper code assignments. As explained above, to secure an appropriate APC for a new technology could take over two and a half years.
2. *Orphan drugs.* Statistically there is no way to account infrequently used but higher-cost products in a prospective payment system.
3. *Cancer treatments.* The proposed rule specifies four different APCs that include 69 different chemotherapy related codes. The APCs do not account for the variances in dosing that occur in actual chemotherapy administration.
4. *Outlier drugs.* Drugs and biologics are at high-risk of not being provided to beneficiaries who need them most. HCFA acknowledges in the preamble to its proposed rule that certain drug products may not fall into any of the categories listed and may result in disproportionate costs to hospitals.
5. *Radiopharmaceutical drugs.* Significant flaws in the data have resulted in inappropriate low payment for procedures using these products.
6. *Plasma based therapies.* BIO estimates there are 62 different types of plasma based products or recombinantly produced substitutes in the United States. With few exceptions, the APC system provides no extra payment for these products.
7. *Drugs for end-stage renal disease.* Dialysis patients rely on a vast array of pharmaceutical and biological products. Since some products will not be covered under the composite rate, we believe their access will be curtailed under the proposed APCs.

A more detailed rationale for special treatment of each of these classifications is addressed in the attached BIO comments to HCFA's proposed rule.

CONCLUSION:

During the last several months we have all focused intently on the need for seniors to secure better access to prescription drugs. I find it ironic that the administration is proposing a new Medicare drug benefit while also, in effect, proposing to limit access to drugs that are already reimbursed under Medicare.

Congress did not intend to decrease patient access to life-saving therapies, create incentives for hospitals to use biotech products in a less efficient manner, shift patient treatments to inappropriate settings or decrease incentives to develop new biotech products targeted for indications that affect elderly populations.

I urge you to address this important issue on behalf of the biotech industry and its patients.

Thank you for the invitation to testify. I would be happy to answer any questions.

Health Care Financing Administration
 Department of Health and Human Services
 Attention: HCFA-1005-P
 P.O. Box 26688
 Baltimore, MD 21207-0488

DEAR SIR OR MADAM: Thank you for the opportunity to comment on the Prospective Payment System for Hospital Outpatient Services Proposed Rule published in the Federal Register on September 8, 1998 (63 FR 47552). The Biotechnology Indus-

try Organization (BIO) is a industry organization representing 850 member companies that research and manufacture a diverse range of biotechnology-derived products, including drugs, vaccines, blood derivatives and related products, tissue-based products, and *in vitro* diagnostic products (hereinafter "biotechnology products and drugs").

After careful review and analysis of the proposed rule and in response to the Health Care Financing Administration's (HCFA's) request for comments, BIO is seriously concerned that the proposed Ambulatory Payment Classification (APC) system would disrupt access to quality health care and create severe underpayment for a broad range of biotechnology drugs and products. BIO believes that sufficient problems exist with respect to the methodologies used to compute APC payments as well as the concept of bundling drugs and biologics that we ask the HCFA administrator to urge the secretary of HHS to assert her authority and carve out several categories of drugs and biologics from the APCs.

BIO believes that the result of bundling drugs and biologics into APCs will decrease Medicare patients' access to quality health care. The current proposed bundling of biotechnology products and drugs into the APC groupings would create a grossly inadequate payment for these products, which is likely to result in:

- decreased patient access to important and often life-saving therapies
- incentives for hospitals to use biotechnology products and drugs in a less efficient manner
- a potential shift of patient treatment to less intensive settings, such as physician offices, even when it is not clinically appropriate and
- significantly decreased incentives to develop new biotechnology products targeted for indications that affect elderly populations.

We believe the rule's potential negative effects provide ample reason to question the proposed system's treatment of biotechnology products and drugs. When considered together, the threat of such disruptive and negative effects on health care makes it imperative that HCFA not bundle biotechnology products and drugs into the APCs.

In these comments we ask the HCFA Administrator to urge the HHS secretary to exercise her exemption authority with regard to biotechnology products and drugs. The Balanced Budget Act (BBA) of 1997 requires HCFA to establish groups of covered services that are comparable clinically and with respect to the use of resources.¹ In addition, the BBA grants the secretary authority to exempt certain products or services from the outpatient PPS.²

As detailed below, it is readily apparent from HCFA's methodology that the costs of biotechnology products and drugs were not carefully considered and in some cases were specifically ignored, in the formulation of the APC system. In addition, we believe the underpayment for biotechnology products will lead to frequent substitution of less clinically appropriate therapies. Accordingly, we propose that HCFA exercise its discretion under the BBA to exempt certain classes of biotechnology products and drugs.

In these comments BIO will explain: 1) our members' concerns with the flawed data collection process and data categories; 2) possible carve-outs that will mitigate the harm to patients who depend on the products they receive in the hospital outpatient setting; and 3) other issues of concern to the industry.

Seven categories of possible carve-outs and examples are detailed in these comments: 1) "New" technologies; 2) "Orphan" drug products; 3) Chemotherapy agents and related supportive care drugs; 4) Biologics and drugs at high risk of not being provided to beneficiaries who need them; 5) Radiopharmaceuticals and other drugs required for nuclear medicine procedures; 6) Blood-derived products; 7) Drug products not covered by the ESRD composite rate.

If there are any questions, BIO and its member companies will be pleased to work with HCFA to find a solution. If there are any questions about these comments, please call Nancy Bradish Myers at (202) 857-0244. Again, we appreciate the opportunity to comment on the proposed rule.

NANCY BRADISH MYERS
Healthcare Policy Counsel

¹ Social Security Act (S), § 1833(t)(2)(B).

² BBA authorizes HCFA to designate the hospital outpatient services to be covered at PPS rates, as amended § 1833(t)(1)(B)(i).

MAJOR CONCERNS WITH THE PROPOSED RULE:

Given the serious underpayment that will occur under the proposed APCs, BIO does not believe that an adequate remedy exists to cover biotechnology drugs and vaccines within the APC framework.

In May of 1998, we shared our early concerns on the prospective payment system (PPS) for hospital outpatient care with HCFA Administrator Nancy Ann Min De Parle. Although we were never granted a meeting with the administrator, our letter stressed our concerns that including biotechnology products in such a system would be inappropriate and could jeopardize the quality of care received by Medicare beneficiaries. Specifically, we were concerned that an outpatient PPS would lead to drastically reduced hospital payments, which would seriously inhibit the ability of hospitals to continue to provide high quality treatment and patient access to necessary health-care services.

We believe that these same issues are even more problematic in the proposed APC rule than we had anticipated in our earlier correspondence. Following the September 8 publication of the proposed rule, we analyzed the new PPS and held detailed discussions with our member companies on its potential impact. Many of our members conducted detailed analyses of payment levels under the proposed APC system, and found them to be woefully inadequate to cover the basic costs of care. In some cases the payment for services is inadequate even before the costs of biotechnology products are considered.

THE PROPOSED RULE'S DETRIMENTAL EFFECTS TO HEALTH CARE

As proposed by HCFA, the APC system could penalize hospitals for providing the most clinically appropriate therapies.

The proposed APC system will threaten patients' access to important and often life-saving therapies because it does not allow adequate payment for most biotechnology products and drugs and their related services. Because HCFA's methodology in deriving APC payment weights excluded all products that received codes after 1996 as well as products judged to be extremely costly, APC payments do not accurately reflect the actualized costs of care. This underpayment—or lack of payment altogether—for biotechnology products and drugs would inhibit hospitals' ability to provide care that relies on these technologies. This would be the case particularly in hospitals that have case mixes requiring heavier utilization of biotechnology products and drugs.

Medicare beneficiaries' access to biotechnology products and drugs should not be determined solely on cost. Nevertheless, the APC system may force outpatient departments to make decisions based primarily on economics and, consequently, deny Medicare beneficiaries access to medically necessary and appropriate care. Clearly, this was not the intent of Congress when it mandated a prospective payment system for hospital outpatient department services.³

Clinicians must be able to determine the most appropriate setting of care for a given patient without being adversely influenced by inappropriate payment.

By not providing adequate payment to hospitals, the APC system will create an incentive to shift care to inappropriate settings.

Since the proposed APC system would severely underpay hospital outpatient departments for a broad range of services that include biotechnology products and drugs, it is reasonable to expect that many patients will lose the option to receive their care in hospital outpatient departments. Physicians will be obligated to treat these patients in alternative sites, whether or not these alternatives are the best setting of care for the procedure involved.

This shift in setting is a problem because hospital outpatient departments can provide a full range of outpatient services, including invasive procedures and expensive specialized care. At the same time, hospital outpatient departments offer a "safety net" through their immediate access to a broad range of clinical specialists and to inpatient services, if necessary. Because physician offices and other settings do not offer this safety net, many services cannot be safely shifted outside of the hospital outpatient setting.

To treat all patients with the most effective, appropriate care, physicians need the flexibility to determine the best setting in which to treat each patient they serve. Many physician offices are not adequately staffed or equipped to provide prolonged infusions, do not have adequate storage and processing capabilities for biotechnology

³The BBA instructs HCFA to create a prospective payment system that ensures payment groupings for services that are "comparable clinically and with respect to the use of resources." See Social Security Act, As Amended, § 1833(t)(2)(E).

products, and lack the financial resources to maintain expensive capital equipment and other materials that are used concurrently with these products.

If APCs prompt a shift in care settings, patients in rural areas may lose access to care completely.

BIO is also concerned that the proposed APC system would disproportionately impact access to care in regions (particularly rural areas) where hospital outpatient departments are the exclusive providers of technology-based services. Because of the acquisition costs, storage and processing, many biotechnology products and drugs can only be supplied by providers that have substantial operating budgets. It simply is not realistic to expect that physician offices in these regions will be able to provide the full range of biotechnology products and drugs currently available in hospital outpatient departments. Accordingly, rural hospital outpatient departments either will have to discontinue stocking essential products and refer patients to larger urban hospitals or sustain substantial losses to provide immediate access to care.

Because the proposed APC system could haphazardly shift patient care to inappropriate settings, it may actually increase costs for certain types of patients.

The shifting of patients from hospital outpatient care departments to other health-care settings because economic constraints may lead to increased Medicare expenditures overall. Beneficiaries who lose access to appropriate outpatient care and subsequently go without therapy may suffer from complications that could otherwise have been avoided. Similarly, beneficiaries forced to receive care in inappropriate settings, such as a physician's office, or who do not receive the optimal therapy because of choice of setting also may suffer from preventable complications. In other cases, beneficiaries may be hospitalized simply because they cannot receive the therapy they need on an outpatient basis—which will increase Medicare costs.

Clearly, the shifting of patient care appears reasonably likely because of the underpayment of APC groups in the hospital outpatient setting. This will reduce quality of care, endanger patient outcomes and, ultimately, lead to greater expense for Medicare.

THE PROPOSED APC SYSTEM'S IMPACT ON DEVELOPMENT OF CRITICAL THERAPIES

The APC system would directly impede the development and adoption of new technologies.

Under the proposed rule, a new technology's APC assignment will not reflect its costs for several years after it is assigned a unique HCFA Common Procedure Coding System (HCPCS) billing code. First, the technology will be billed with a miscellaneous HCPCS code and will be assigned to the lowest paying APC available. Once a unique HCPCS code is assigned, HCFA proposes to determine which APC includes services that are most similar clinically and with respect to resources to the new technology. If several APCs are identified, HCFA will assign the new technology to the lowest paying option without adjusting the relative weight or payment amount of the recipient APC. Only after an additional period of at least two years will the technology be eligible for assignment to the most appropriately paying APC.⁴ Therefore hospitals will not be able to offer their patients access to the breakthrough products of the day because of the financial risk to the hospital. This will lower the standard of care for Medicare beneficiaries.

The proposed recalibration approach for updating APC weights may not allow hospitals to cover the cost of new technologies for several years.

The inequity of purposely assigning new technologies to the lowest paying APCs is compounded by the fact that Medicare proposes to update APC assignments only after two or more years of data collection and to recalibrate the payment levels of each APC infrequently. The result of HCFA's proposed updating methodology is that an APC that includes a new technology may not be assigned an appropriate weight for more than three years. This delay could have a chilling effect on the evolution of medical care and therefore on the quality of care available to beneficiaries.

Given that new technologies often drive rapid changes in medical practice, as has happened in the treatment of AIDS/HIV and cardiovascular medicine, BIO strongly believes that the APC system should not include drugs and biologics. In the unfortunate event that the APC system continues to house biologics and drugs, it must be recalibrated to establish a realistic baseline payment for each APC case that reflects all inputs including *each* drug and biotherapeutic and *then* recalibrated at least annually to reflect the current advancements in patient care.

⁴The preamble to the proposed rule states that HCFA will not create an APC for an entirely new code, but will assign it for at least two years to an existing group while accumulating data on its costs relative to the other codes in the APC (63 FR 47579).

In addition to adversely affecting beneficiary care, the proposed recalibration methodology would harm small, innovative biotechnology companies because it would keep them from successful product commercialization.

The development of life-saving therapies depends on the ability of biotechnology companies to achieve a return on their investment of resources. At present, we estimate that it takes our member firms an average of eight years and over \$350 million to bring a novel biological product to market. Accordingly, it is critical that a new technology be assigned to a clinical and resource-appropriate APC immediately upon its market availability, and that the assignment not act as a disincentive to the product's use. To institute a system that does otherwise would threaten Medicare beneficiaries' access to medically appropriate care.

The proposed APC system would create substantial disincentives to private sector development of such products.

New biotechnology products and drugs often are breakthrough technologies that offer treatment to patients who have few other options. However, by their very nature, many are costly to develop and produce. HCFA has not taken this into consideration when developing its APC system. Instead, it insists on bundling biotechnology products and drugs into APC payments, thereby not allowing hospitals to adequately cover their costs. Not only will this hinder clinical adoption of biotechnology products and drugs, but it also will affect the advancement of these therapies into the standard clinical practice of medicine. As a result, the currently proposed APC system could significantly decrease the incentives to develop new biotechnology products and drugs targeted for indications that affect the elderly population. Clearly, this is not in the best interest of Medicare beneficiaries.

The APC system is highly likely to affect access to new therapies for non-Medicare patients as well. This will occur for two reasons:

First, it is widely anticipated that private payors will follow HCFA's lead and implement APCs, first in the hospital outpatient setting and quickly thereafter in the physician office setting. The consequence of rapid, all-payor implementation of APCs would inevitably be to skew drug development toward high-volume, low-cost products, the only ones for which APC-based reimbursement could possibly be adequate. Any incentive to develop innovative, potentially higher costs biotherapies would be gone.

APCs also create a second, more subtle risk issue. To the extent that drug sales and revenues decrease lack of reimbursement under APCs for both Medicare and private payors, investors are unlikely to make funds available to develop and bring innovative yet costly drugs to market.

Underpayment for new technologies under the proposed APC system flies in the face of other government programs specifically intended to accelerate the development and availability of life-saving therapies.

As a result of federal technology transfer laws, in 1997 U.S. universities received approximately \$338 million in gross license income for licensing out technologies in the life sciences to facilitate development of these technologies into drugs, biologics, vaccines or other products. In addition, with the implementation of FDAMA, signed by the president, the Food and Drug Administration has implemented numerous initiatives aimed at speeding new product reviews, in essence to allow patients faster access to new therapies. For example, under the Prescription Drug User Fee Act of 1992, FDA must complete its reviews of new biological product applications within strict, 12-month time frames. It would be a tragedy, now that we have begun to finally achieve faster FDA reviews of new biotechnology products and drugs, and substantial public support of biotechnology products and drugs research, to see these efforts negated by impediments created by a poorly designed APC system.

MAJOR FLAWS IN HCFA'S METHODOLOGY FOR ANALYZING CLAIMS DATA, PARTICULARLY IN TERMS OF BIOTECHNOLOGY PRODUCTS AND DRUGS

We strongly believe that HCFA's data methods systematically underestimates the costs of providing biotechnology products and drugs. We reviewed the release of additional data in June 1999, a year and a half after the original proposed rule, and our concerns remain just as strong.

Multiple procedure claims were excluded from the proposed APC weight-setting calculation despite that fact that these claims likely represent patients who are the least healthy and require more costly services.

As described in the preamble of the proposed rule (63 FR 47573) and confirmed in subsequent meetings with HCFA, its analysis for determining APC weights relied on only single-service claims. It did not analyze claims that represented multiple procedures. Clearly this fundamental flaw in the analysis skewed the APC weights,

essentially to reflect care for only the healthiest patients. Patients requiring multiple outpatient services on the same date of service are likely to be the least healthy and are likely to require more costly care than patients who receive a single outpatient service.

In addition, we believe the single-procedure focus HCFA used may have excluded a disproportionate number of biotechnology products and drugs, because many of these products are routinely used as part of multi procedure, combined-treatment regimens. By systematically eliminating these cases in its methodology, HCFA has inadvertently biased the APC system against biotechnology products and drugs and derived payment levels that do not reflect the true costs of care across the Medicare population.

Dismissing "outlier" claims in its calculation of APC weights also likely removed biotechnology products and drugs from the analysis and therefore under reimburses other categories.

In calculating APC weights, HCFA disregarded claims for services with costs more than three standard deviations from the geometric mean. Although HCFA may have found a statistical basis for this exclusion, we believe that it systematically excluded biotechnology products and drugs that are often expensive, but vital, components of patient care. As a result, this procedure results in lowered payment levels that disproportionately affect biotechnology products and drugs.

Because of inadequate coding practices, HCFA was unable to allocate the true costs of most drugs used for Medicare beneficiaries.

In the preamble to the proposed rule, HCFA describes its inability to capture the costs of drugs, other than chemotherapeutic agents, because of inadequate coding practices, under the precursor Ambulatory Patient Group (APG) system. HCFA acknowledges that participating hospitals in the APG system were obliged to consistently use HCPCS codes only for chemotherapeutic agents. HCFA did not require detailed coding of other drugs and, as a result, "cannot specifically identify the costs" of these products.⁵ Further, HCFA requests comments on how to remedy this problem, recognizing that problems may exist for hospitals that treat patients with very costly drugs or biologicals.

Although we credit HCFA for identifying this limitation, BIO believes that HCFA dramatically understates the degree to which it represents a critical flaw in the APC payment system. First, the APCs do not merely underpay "a few" hospitals that treat patients with "very costly" drugs and biotechnology products—the system will underpay all hospitals for a vast range of routine infusion-based therapies and other drug-intensive care. While costly biotechnology products and drugs are disproportionately affected, we believe that treatment with nearly every biotechnology product produced by our members will be affected through the underpayment of the APC system.

Second, HCFA reaches an unfounded conclusion that since drugs usually are provided in connection with other treatments or procedures, the costs of these products can be reasonably packaged into other procedure-based groups. BIO finds this assumption patently absurd. The aberrant and biased method of selecting single-service claims makes it extremely unlikely that the bulk of drug utilization patterns and costs have been captured in the APCs. In the case of the infusion APCs, it is reasonable to assume, based on HCFA's methodology, that the cost of most biotechnology drug products were not factored into the agency's analysis because of inadequate coding practices.

HCFA should not extend a PPS system to services or products for which it has no basis to understand actual costs or utilization.

The inherent bias used in selecting claims for analysis, along with the absence of detailed coding data for non-chemotherapeutic drugs and biologicals, essentially means that the proposed APC system has no real basis in actual costs or patterns of care for biotechnology products or drugs. BIO believes that this is the case for both procedure-based APCs as well as infusion-based therapies.

Solution:

THE HCFA ADMINISTRATOR SHOULD ASSERT HER EXEMPTION AUTHORITY TO NOT INCLUDE DRUGS AND BIOLOGICS IN THE APCs.

The Balanced Budget Act (BBA) of 1997 requires HCFA to establish groups of covered services that are comparable clinically and with respect to the use of resources.⁶ In addition, the BBA grants the secretary authority to exempt certain

⁵ Preamble to the proposed rule (63 FR 47563).
⁶ Section 1833(t)(2)(B) Act (BBA), as amended 1997.

products or services from the outpatient PPS⁷. The HCFA administrator should exercise her explicit exemption authority with regard to biotechnology products and drugs since it will seriously affect Medicare beneficiaries' access to several categories of products.

THE SECRETARY OF HHS SHOULD AT A MINIMUM CARVE OUT CERTAIN KEY PRODUCT CATEGORIES FROM THE APCs.

The HHS secretary has the authority to designate the services to be included or excluded from the outpatient PPS. Although we believe it is most appropriate for the secretary to carve out all drugs and biologics from the APC system, we have tried to identify more limited categories of products that would be disproportionately hurt under the proposed APC system. While BIO acknowledges that broader, systemic problems may still occur under the APC framework, we believe that it would be appropriate for seven types of products identified below to be carved out in order to address the most serious payment shortfalls in the proposed system. The seven categories are:

1) **"New" technologies should be paid separately from the APC system until adequate coding allows for proper reimbursement.**

As described above, new technologies will not experience appropriate levels of reimbursement for several years after they become available for use. This delay in adequate payment could artificially delay the full adoption of new technologies because hospital outpatient departments would lose money with each use. Clearly, such an approach does not adequately take into consideration the resources involved in developing new technologies and would impede their development and adoption.

Accordingly, HCFA should automatically reimburse new therapies using the current payment mechanism during the entire period that the product awaits proper HCPCS and APC code assignment.

CASE example: The I-131 Anti-B1 Antibody is a radiological monoclonal antibody that is expected to be approved for the treatment of non-Hodgkin's Lymphoma. This product is expected to be the first radioimmunotherapeutic product approved for the treatment of cancer and has been shown to produce remission of cancer of longer duration than standard chemotherapy. Unfortunately, this promising new product will be assigned a miscellaneous CPT (CPT code 7999, unlisted radio-pharmaceutical therapeutic procedure) and placed in the lowest paying radiological APC (APC 791, \$757.93). For a period of several years, this product would remain in APC 791 with no additional payment and then, if warranted, could be redesignated to a higher paying nuclear medicine APC.

2) **"Orphan" drug products should be paid separately from the APCs because the APCs will delay and possibly deny patients access to life-saving products.**

The Orphan Drug Products Act provides for a special marketing approval status for certain products that treat life-threatening, rare diseases. Many of these products are the result of years of research, involving clinical trials with hundreds of patients. By definition, products afforded orphan approval status by the FDA offer patients with severe debilitating illness a chance for significant therapeutic benefit. Typically, these products are afforded special review status at the FDA in order to expedite review and approval, so that patient populations will not be denied a viable treatment.

CASE EXAMPLE: A breakthrough orphan drug product, Infliximab; MAb, tumor necrosis factor alpha, is indicated for Crohn's disease, a chronic form of inflammatory bowel disease. At present, a supplemental indication is pending approval for rheumatoid arthritis. A typical course of therapy for Infliximab involves an infusion over a two-hour period once every eight weeks. The drug used in a typical infusion costs \$1,800, yet APC reimbursement as proposed would equal only \$73.98 for infusion of the drug. If hospitals are obliged to absorb most of this drug cost because of the proposed APC system, it seems likely that far fewer providers will make Infliximab available to patients even though a provider might determine it to be the best treatment.

BIO believes that the impact of the APC system, in delaying proper code assignment and providing severe underpayment for most orphan products, will essentially negate the valuable benefits of orphan status. In some cases, patients who cannot afford to supplement Medicare's underpayment will literally bankrupt themselves to gain coverage, or they may be forced to forgo these valuable therapies.

3) **Chemotherapy agents and related supportive care drugs should be paid separately from the APC system.**

⁷The BBA authorizes the secretary to designate the hospital outpatient services to be covered by the outpatient PPS, see SSA, as amended § 1833(t)(1)(B)(i).

The proposed rule specifies four different APCs that include 69 different chemotherapy related HCPCS codes. For specific chemotherapy agents, providers would be able to bill for the appropriate code, along with an infusion procedure APC. Although a number of the chemotherapy agents are listed more than once in the different chemotherapy APCs to account for different dosage levels, the APCs do not nearly account for the variances in dosing that likely would occur in actual chemotherapy administration. In addition, some chemotherapy agents do not have HCPCS codes that specify dosing at all. As a result, payment for some chemotherapy agents may be inequitable, depending on the dosing used.

In addition, the chemotherapy APCs do not account at all for the costs of biotechnology drugs and products that are used concurrently during chemotherapy. As proposed, the APC system would compensate hospitals for only a fraction of the costs incurred for chemotherapy patient care, through the billing of infusion codes for each hour of infusion time. Clearly, the APC system would have dramatic impact on the availability and quality of patient care for severe cancer cases. As such, it is important not only that all cancer-related drugs be paid separately, but that the payment for chemotherapy agents and those products used in relation to cancer care be reimbursed adequately.

CASE EXAMPLE: Many patients undergoing chemotherapy for treatment of their cancers receive supportive care drugs to treat neutropenia, anemia or nausea or vomiting. Myelosuppressive cancer patients receive erythropoietin injections from their physicians to treat their anemia secondary to their chemotherapy treatment and restore the hematocrit level. Patients may receive Filgrastim, a human colony granulocyte stimulating factor in order to restore neutrophil counts and treat their neutropenia. Under the APC system, these products and other growth factors are classified as incidental, so hospitals would be reimbursed only for their administration, as little as \$38.05 if injected or \$99.24 if infused intravenously, not covering the cost of either of these therapies. For example, a typical course of Filgrastim can cost \$322 per day for up to two weeks. This reimbursement would not cover the cost of a routine course of therapy.

4) Biologics and drugs at high risk of not being provided to beneficiaries who need them also should be paid separately from the APC system.

As HCFA acknowledges in the preamble to the proposed rule, certain drug products that may not fall into any of the categories listed above may result in disproportionate costs to administering hospitals. While HCFA refers to the possibility of a fee schedule in the preamble, it also acknowledges that fee schedules create unnecessary administrative burdens for hospitals. BIO concurs that a fee schedule approach for costly drugs would not serve the provider community. BIO urges that HCFA continue to pay for these products as they are currently paid for.

CASE EXAMPLE: Immune Globulin Intravenous (IGIV) is a solution of immune globulins containing human antibodies. This biologic product is used to treat a variety of patients who have deficient or dysfunctional immune systems. IGIV is a large protein molecule that when administered should be closely monitored for adverse reactions. Some patients, with a history of complications and transfusion reactions and those with comorbidities should receive their initial few months of infusion therapy in a hospital outpatient department where their condition can be closely monitored. The proposed APC payment of \$99.00 would not be sufficient to cover the costs of IGIV therapy. If hospital outpatient departments are not reimbursed appropriately for IGIV infusions, the infusions may be shifted to other, maybe less clinically appropriate settings.

5) Radiopharmaceuticals and other drugs required for nuclear medicine procedures will be disproportionately underpaid and should be paid separately from the APC system.

BIO is concerned with the levels of payment for nuclear medicine, generally, and severe errors in the calculation of related APC weights. The proposed APC relative weights that would cover radiopharmaceuticals are clearly erroneous, as they would provide for higher payment for a standard therapeutic nuclear medicine procedure (APC 791—\$757.93) than for a complex nuclear medicine procedure (APC 792—\$247.33). Further examination of the baseline data used by HCFA to compute appropriate weights for APC 791 and APC 792 also suggests that a broad range of inappropriate or miscoded charges were included in HCFA's analysis.⁸

BIO also is concerned that the proposed APC system would severely underpay certain radiopharmaceutical products.

⁸ According to public use data released by HCFA on its Internet web site, CPT 7999, one of the most common codes for nuclear medicine procedures, had a cost range of 175 sampled claims was \$2.51 to \$2,452.77. In other CPT codes that map to APCs 791 and 792.

Accordingly, BIO is concerned that baseline payment levels for nuclear medicine APCs are inadequate, and that radiopharmaceuticals need to be reimbursed on a reasonable cost basis.

6.) Blood-derived products should be paid separately from the APC system.

The proposed APC system would systematically underpay a broad range of blood products and technology-intensive blood derivatives. At present, BIO estimates that there are 62 different types of blood-derived products, or recombinantly produced substitutes, produced and sold in the United States. With few exceptions, the APC system provides no extra payment for these products, either because they are classified as incidental or because they do not have specific HCPCS codes.

CASE EXAMPLE: Hemophilia A is an inherited, lifelong blood clotting disorder that is caused by a deficiency of a plasma protein called Factor VIII or Antihemophilic Factor (AHF). The mainstay of successful treatment and prevention of bleeding for patients with hemophilia A is a prompt and sufficient treatment with AHF concentrates. The typical hospital cost for a course of treatment with a recombinant form of AHF can range from \$500 to well over \$4,000 per intravenous injection. Under this current proposal, payment for this advanced biologic would be bundled into an injection APC of \$43. By virtue of its expense, all claims for AHF and other coagulation concentrates were eliminated from APCs because they fell outside of the allowed standard deviations from the geometric mean. BIO believes that very few, if any, hospitals in the country could reasonably afford to suffer the recurrent losses they would incur by offering this therapy for each patient treated.

As described above, underpayment for Factor VIII offers an example of how the proposed system would penalize hospitals for treating the most severely ill patients, and particularly discourages treatment with more costly, but clinically appropriate therapies. Accordingly, HCFA should pay for Factor VIII and all other blood-derived products on a reasonable cost basis.

7) Drug products not covered by the ESRD composite rate should be paid separately from the APC system.

In the proposed rule, HCFA indicated that it was exploring ways to accurately reimburse for drugs used outside the ESRD compensation rate. This is a complicated issue; however, BIO would recommend a carve-out similar to others we've proposed. Dialysis patients rely on a vast array of pharmaceutical and biological products targeted to the patient and his or her needs. Since some products will not be covered under the composite rate, we believe their access will be curtailed without a carve-out for those products used in the hospital-based dialysis facilities.

GENERAL STATEMENT ON IMPLEMENTATION OF THE HOSPITAL OUTPATIENT PROSPECTIVE SYSTEM:

Phase-In Requirement:

If there is no carve-out for all biologics and drugs, the outpatient must be phased-in.

As stated in the preamble to the proposed rule, HCFA intends for the APC system to prompt hospitals to provide services in a more cost-conscious manner, as was the case following implementation of the diagnosis-related group (DRG) system for inpatient care.⁹ We believe there are critical differences between the DRG and APC systems and the services they affect, particularly in the economics of patient care and the potential for savings. Where the DRGs realized substantial savings by reducing the lengths of inpatient hospital stays, no such savings are possible for outpatient services. Indeed, many services formerly provided in the inpatient setting are now provided outpatient, thanks to advances in biotherapy. In addition, it is likely that the costs of biotechnology products and drugs represent a greater proportion of outpatient care costs than they do of inpatient care costs. As a result, outpatient departments will face greater payment shortfalls than inpatient departments experienced with DRGs, but will have far less opportunity to reduce overall costs of care.

Another important difference between the DRG system and the proposed APCs is that the proposed APC system is largely untested, yet will not be phased in. This means that any defect in the APC system's design could significantly negatively hurt care with unknown and unpredictable consequences for millions of Medicare recipients.

Finally, any disruption in patient care due to the APCs implementation will occur without the availability of viable alternative settings to absorb patients. When the DRG system was implemented, many hospitals were able to shift certain types of

⁹The preamble to the proposed rule makes several references to the inpatient PPS, see 63 FR 47554, 47557.

care to outpatient departments. Under the APCs, there will be no alternative hospital-based setting to absorb these outpatient cases.

Accordingly, it is essential that economic constraints under a new outpatient PPS not force hospitals to choose between providing these services at a huge loss, shifting them to inappropriate less intensive care settings, admitting patients when it is not necessary, or not providing the service, at all.

Volume Control Measures:

The proposed volume expenditure caps will exacerbate the access problems created by this proposed rule. These caps should be eliminated from the outpatient PPS.

Volume expenditure caps, as included in this proposed rule, will force hospitals to bear the cost in changes in cost of care. Under the proposed caps, annual updates to hospitals could be reduced if Medicare spending for outpatient services exceeds HCFA estimates. This means that if overall outpatient costs increase, hospital reimbursement could be cut. This will have a great impact on a hospital's ability to utilize new technologies or even the most appropriate technologies for fear of hitting the volume expenditure caps. This will affect quality of care tremendously.

We suggest HCFA explore other ways of controlling what it deems to be unnecessary volume. Arbitrary caps on the outpatient setting will slow down how and where new medical technology is used. Over the last several years, many procedures and much therapy delivery have migrated to the hospital outpatient setting because it was considered more appropriate and less costly. To put arbitrary volume caps on the outpatient setting could shift more care to the inpatient setting and therefore increase costs to the Medicare program.

SUMMARY OF RECOMMENDATIONS

In view of the extensive and systemic problems in deriving APC weights and APC groups, BIO urges that the HCFA administrator carve out biologics and drugs from the proposed APCs. We recommend that HCFA carve out seven categories of products. It is reasonable to expect that any revised prospective payment method will not adequately reimburse providers for the use of products in these categories listed below:

- 1) "New" technologies that are awaiting proper HCPCS and APC code assignment.
- 2) Orphan drug products.
- 3) Chemotherapy agents and related supportive care drugs.
- 4) Biologics and drugs at high risk of not being provided to beneficiaries who need them most.
- 5) Radiopharmaceuticals and related drugs.
- 6) Blood-derived products.
- 7) ESRD-related products not paid under HCFA's composite rate.

We also recommend that HCFA phase in this hospital outpatient PPS system gradually since much of the data necessary to establish a valid system has not been collected to date.

We also urge HCFA to eliminate volume expenditure caps from the outpatient PPS.

BIO looks forward to working collaboratively with HCFA in revising its proposed APC system, in order to better serve the needs for quality care of the Medicare population.

Thank you for this opportunity to comment on this proposed rule. BIO and its member companies will be pleased to work with HCFA to find a solution. If there are any questions about these comments, please call Nancy Bradish Myers at (202) 857-0244. Again we appreciate the opportunity to comment on the proposed rule.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

BIO is the largest industry organization to serve and represent the biotechnology industry. Our membership comprises the world's producers of important medical innovations, including recombinant products, blood products and related derivatives, and in vitro diagnostic tests. In total, BIO's membership includes 835 companies, 150 academic and state biotechnology centers and related organizations in 47 countries and more than 20 nations. These member firms are located in 150.0 in the United States, with over two-thirds of our members having fewer than 135 workers. At present biotech companies are heavily involved in human clinical trials and more in early

The products of our member firms span a broad range of life-saving therapies that often are the only treatment options available for patients suffering from life-threatening diseases. Currently, there are 80 biotech drug products and vaccines on the market, many of which are provided in the hospital outpatient department.

Mr. BILIRAKIS. Thank you very much, sir.

Mr. Dingell to introduce Mr. Warden, who has not testified as yet. He has been sitting there very patiently waiting for your introduction.

Mr. DINGELL. It is a great kindness, Mr. Chairman, and I thank you for it.

It is a great pleasure for me to welcome and introduce my good friend Gail Warden, who runs a very fine hospital back home, Henry Ford, and who is not only a distinguished practitioner in the business of hospital administration but also who is very active in all manner of community affairs back home. He is not only a respected citizen of our community but, as I say, runs a superb hospital and is a good friend of my wife Debra and I and Mr. Warden, we are happy to welcome you to the committee.

Thank you for that courtesy, Mr. Chairman.

Mr. BILIRAKIS. You are very welcome, sir.

STATEMENT OF GAIL L. WARDEN

Mr. WARDEN. Thank you very much, Mr. Chairman and Congressman Dingell.

I came to this hearing today prepared as a representative of the American Hospital Association and as one of its former chairmen, as well as a representative of my own institution, the Henry Ford Health System of Detroit. I had planned to make my oral testimony somewhat coincide with what was in the written testimony and to elucidate on it, but I must say that I have been very impressed with the knowledge of the issues of the members of the subcommittee, the homework that they have done and they know the studies that have been done and the discrepancies in those studies and the overshoot that took place in the Balanced Budget Act. So I am not going to spend a lot of time talking about that again.

Instead, I would like to take time to really talk about two things. I would like to, having heard that there had not been as much impact upon quality and access as might have been expected, give you two anecdotes, one about the city of Detroit and another about a hospital in Manistique, Michigan, and then I would like to finish by making some comments about the outpatient PPS.

In the city of Detroit there really are three safety net hospitals: the Detroit Medical Center, the Henry Ford Hospital and a hospital named Mercy Hospital. The combined impact of the Balanced Budget Act and reductions in Medicaid payment upon those three institutions has been substantial. In each case there have been large financial losses and large lay-offs. The Detroit Medical Center has laid off over 2,000 people. Our organization has laid off 800 and will be laying off another 1,000 people.

We have closed clinics, consolidated clinics, reduced services in community-based programs. Generally the challenges continue to get greater and we are both experiencing continued increase in uncompensated care and the amount of uninsured, with the L A

Medical Center having about \$120 million in uninsured care and our organization about \$60 million.

The third institution, Mercy Hospital Detroit, has been similarly impacted but they do not have the resources or reserves to fall back on and there is a very good chance that they are going to close. What it is going to mean is that in order to maintain access to those institutions for the people in the city of Detroit is that our two institutions are going to have to come together and try to find some way to make that happen. So my point is that the urban safety net is being impacted by the Balanced Budget Act.

Second, in the case of the hospital in Manistique, it is the sole provider within a 70-mile radius. The impact of the Balanced Budget Act on them was about 10 percent and the one program that is threatened right now is obstetrics. If they are to close their obstetrics unit, there will be no obstetrics and gynecology program for at least 70 miles in any direction. Again it is a product of the impact of the Balanced Budget Act on that particular institution.

In relationship to the outpatient PPS, I would like to talk about three specific concerns. The first one obviously has been discussed on a couple of occasions today, that the original projection by the Medicare Payment Advisory Commission was that hospitals will currently pay 90 cents on the dollar and that under BBA they would be paid about 82 cents on the dollar. We also heard today about the additional 5.7 percent reduction that HCFA plans sometime in the near future.

We also heard about the 255 members of the House and 77 members of the Senate who have signed on to bring about some relief from that and we are particularly impressed with the bill that Representative Foley has introduced, which would cap outpatient losses at 5 percent at the current rate, 10 percent in the current year, 10 percent in the second year and 15 percent in the third year.

The second issue that we are concerned about relates to something that is kind of hidden in the regulation which relates to provider-based provisions. It impacts organizations like ours, the Cleveland Clinic and Johns Hopkins, organizations who, in an effort to try to bring care closest to the community in a fairly large service area, have developed ambulatory care centers. But the provision says that these must be licensed by the State and in most cases they are in States that do not license these facilities as outpatient facilities because they are extensions of the hospital. We believe that consideration should be given to a joint commission of accreditation as a proxy.

The third consideration that we want to raise is about the data that HCFA used to calculate payment under outpatient PPS. In my own organization's case, the HCFA estimate was that we would have a \$1 million increase in income. Our detailed analysis identified several discrepancies in the estimate which are related to the fact that the information did not dig down deep enough. Only about 30 percent of the services provided were not accounted for and we calculate the impact is going to be about a \$9.6 million loss.

If you combine that with the losses that we have already experienced in the Balanced Budget Act and the losses of \$12-\$25 million result of the provider payment provisions,

it adds up to a substantial amount and will make our reduction in revenue for Medicare for a 5-year period somewhere in the neighborhood of \$225 million, which seems just too much if we are going to continue to maintain our safety net provider role. I thank the committee very much for the opportunity to talk to you.

[The prepared statement of Gail L. Warden follows:]

PREPARED STATEMENT OF GAIL WARDEN ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. Chairman, I am Gail Warden, president and CEO of Henry Ford Health System in Detroit, and former chairman of the American Hospital Association (AHA). I am here today representing the AHA's nearly 5,000 hospitals, health systems, networks, and other providers of care. We appreciate this opportunity to present our views on an issue that is dramatically affecting hospitals in communities across America: The Balanced Budget Act of 1997 (BBA). Our testimony focuses primarily on how the act is affecting Medicare payments for outpatient services. But first I'd like to review the overall effects of the BBA on hospitals and health systems.

OVERALL EFFECTS OF THE BBA

For over a year, hospitals across the country have been sounding the alarm about problems associated with implementation of the BBA. In all parts of the country—urban as well as rural—we are documenting service closures and cutbacks as hospitals and other health care facilities attempt to wrestle with the BBA's dramatic reductions.

The BBA mandated the largest changes in Medicare since the program's inception in 1965. In addition, the budgetary impact of these many changes were vastly underestimated. A study conducted by The Lewin Group found that the originally estimated five-year BBA hospital payment reduction of \$53 billion is, in reality, more in the range of \$71 billion—an \$18 billion increase. And the Congressional Budget Office (CBO), in its July 1 estimate of federal revenues and spending, reported that the Medicare payments will total \$206 billion less than CBO predicted when the act was adopted.

Given this massive change and the disruption it is creating, we urge Congress to enact the following initiatives, funded through the budget surplus. These initiatives represent a broad-based relief effort—an effort that would provide effective relief not just for hospitals, but for a variety of health care providers who take care of Medicare beneficiaries in several different settings.

Transfer policy—Medicare patients sent from one acute care hospital to another are defined as transfers. Under the BBA, HCFA defines transfers to include cases where a patient in one of 10 diagnosis-related groups (DRG) chosen by HCFA, stays in the hospital at least one day less than the national average and then is sent to one of several post-acute care settings. In the past, hospitals received the full Medicare DRG payment for each discharge under PPS, regardless of the patient's length of stay. Payments for cases shorter than average stays help defray the costs of caring for patients with longer than-average stays. This rule of averaging is one of the fundamental principles upon which PPS was built. *AHA urges you to repeal the unnecessary and unwarranted transfer provision by adopting H.R. 405.*

Advances in science and technology—the Medicare Payment Advisory Commission (MedPAC) has reported that hospitals will "incur significant operating and capital costs in becoming year 2000 compliant." As a result, MedPAC has recommended that a modest increase in hospital inpatient payments be made to help offset the costs of these improvements to medical devices and information systems. *AHA urges adoption of MedPAC's recommendation for a modest PPS update to compensate hospitals for Y2K readiness activities, through the passage of H.R. 2266.*

Rural relief—Because of their small size, rural hospitals are often unable to absorb the impact of changes in payment and regulatory policies. With the mounting pressures of the BBA, these facilities warrant special consideration, especially considering their role as the hub of the local health care delivery system. *AHA urges relief for rural health care providers—particularly sole community providers, critical access hospitals, and Medicare-dependent hospitals—through the adoption of provisions of H.R. 1344.*

Medical education—This nation's medical schools are often referred to as national treasures. Yet under the BBA, Medicare's indirect payment for medical education is scheduled to be reduced from 7.7 percent to 5.5 percent by FY 2001. We all benefit from the research and medical education conducted in our medical

schools and teaching hospitals, but this reduction is making it difficult for these institutions to maintain their cutting edge prominence. *AHA urges relief for our nation's teaching hospitals by freezing the current schedule on further indirect medical education reductions through the adoption of H.R. 1785.*

Disproportionate share payments—The BBA took an important step by removing hospitals' clinical education payments from Medicare+Choice payments. This move was made to ensure that payments be made to those facilities actually incurring the added costs. Unfortunately, BBA did not remove the important disproportionate share (DSH) payment. This special payment is made to support the additional costs hospitals incur in treating large numbers of low-income individuals. Without this funding, these institutions will experience difficulty in maintaining access to vital health care services for low-income individuals. *AHA urges relief for hospitals serving the uninsured by carving out the disproportionate share payments from the Medicare managed care payment by adopting H.R. 1103.*

Managed care—The BBA set in motion a long-overdue change to the Medicare program by reducing geographic variations in managed care payments. This equity update to Medicare+Choice payments would be accomplished by "blending" the county rate with a national rate, thus reducing the historic variation in Medicare health plan payments from county to county throughout the country. HCFA has had difficulty fully implementing this provision due to the way the law was drafted. *AHA urges the full funding of the Medicare managed care payment blend to provide fair payment in all parts of the country by adopting H.R. 406.*

Long-term care—The BBA reduced skilled nursing facility (SNF) payments by \$9 billion over five years. At the same time, it required HCFA to implement a prospective payment system (PPS) for these services. The new PPS is not refined enough, however, and therefore fails to adequately account for differences in costs associated with the care of medically complex patients. In particular, the payment for non-therapy ancillaries (pharmaceuticals, respiratory therapy and special equipment) is the same proportion across all the categories in the payment system, even though for some patients care costs are much higher.

Both HCFA and providers believe these issues can ultimately be addressed by revising current case-mix categories (Resource Utilization Groups) used in the new SNF PPS to reflect these types of patients. However, HCFA cannot make any changes to case-mix until after 2000, and additional dollars are still needed to mitigate the consequences of the BBA. HCFA has also not completed its research on how to improve case-mix. Based on preliminary research by HCFA contractors, patients in two RUGs categories—"extensive services," which includes patients who need IV feeding, IV medications, or require ventilators, and "special care," which includes patients who have multiple sclerosis, cerebral palsy or require respiratory therapy seven days a week—have much higher non-therapy ancillary costs than other patients. The current payments for these RUGs are far below the costs of providing the services, ranging from a high of 81 percent to 62 percent of costs.

A multiplier could be used to increase the payments for these groups—extensive services and special care—until the final case-mix improvements can be made by HCFA. The multiplier will no longer be necessary once the Secretary refines case-mix and the funding can then be used to fund the revised case-mix format. The multiplier can be implemented regardless of the Y2K restrictions since HCFA already plans on updating the RUG rates in October 1999.

Psychiatric PPS—Cuts to psychiatric services were also included in the BBA. As a result, many hospitals serving the mentally ill will receive payments below previous levels—real cuts. *AHA urges adjustments to payments to psychiatric hospitals in a budget-neutral manner by adopting H.R. 1006.*

Home health—BBA included a number of changes in payment, coverage, and administrative requirements for home health agencies. Until PPS could be implemented, BBA provided for an interim payment system (IPS) designed to reduce payments to home health agencies. The IPS was the first of the BBA's provisions to be implemented and created a number of disruptions in access to services in some areas of the country. *AHA urges that additional funding be targeted to home health providers to minimize the ongoing inequities of the IPS, and lessen the 15 percent payment cut scheduled for the home health PPS in FY 2001.*

LIMITING LOSSES UNDER OUTPATIENT PPS

According to a recent MedPAC report, Medicare reimbursed hospitals only 90 cents for each dollar of outpatient care provided prior to enactment of the BBA. Today, as a result of the BBA, hospitals are paid only 82 cents on the dollar. And after PPS is implemented, HCFA will reduce hospital outpatient payments by another 5.7 percent. However, according to HCFA's own estimates, many hospitals will

lose much more than 5.7 percent. More than half of the nation's major teaching hospitals would lose more than 10 percent; nearly half of rural hospitals also would more than 10 percent.

In addition, catastrophic losses would be experienced by some individual hospitals. For example, large hospitals in Iowa and New Hampshire will immediately lose almost 14 to 15 percent of their Medicare outpatient revenue. Other large urban hospitals in Missouri, Massachusetts, Wisconsin, Florida, and California stand to lose 20 percent to 40 percent. Some New York City hospitals would lose more than 40 percent. Some small rural hospitals in Arkansas, Kansas, Mississippi, Washington, and Texas will lose more than 50 percent of their revenue.

To prevent these precipitous drops in Medicare revenues from doing additional harm to hospitals and the Medicare beneficiaries who rely on them, we urge passage of legislation that would limit payment losses created by the move to outpatient PPS. However, the costs of financing this proposal should not be paid by the remaining hospitals, because most of them are also expected to lose under the outpatient PPS. Moreover, large new losses would have to be incurred by those hospitals, ranging from 3 to 8 percent, to protect other hospitals from losses of 5 to 15 percent. Instead, this change needs to be funded by additional Medicare program spending. Beneficiary spending would be unaffected.

Under our proposal, until January 2002, each hospital's Medicare payments for outpatient PPS services would be adjusted so that the hospital's losses are limited to 5 percent of what the hospital would have been paid by Medicare under the current system. For calendar year 2002, the payment losses would be limited to 10 percent. For CY 2003, the payment losses would be limited to 15 percent. No limit is set after 2003. Depending on whether HCFA changes its interpretation that unfairly shifts the 5.7 percent reduction in beneficiary copayments from the Medicare program to hospitals (see below), this proposal will require roughly \$1.9 billion over five years in new funding.

MedPAC chair Gail Wilensky recently supported phasing in the outpatient PPS, stating "to mitigate unintended effects and help people adjust to the new system, it's wiser to phase in just about any big payment change." In addition, a June 2, 1999 *New York Times* article noted Dr. Wilensky's comment that "Medicare is paying too little for outpatient services." The AHA agrees, and urges your support for legislation that would provide such a payment "floor" and protect hospitals from unreasonable losses during the transition to outpatient PPS. *Such legislation (H.R. 2241) was introduced in June by Rep. Mark Foley (R-FL), and has 68 co-sponsors. We urge you to support it.*

REGULATORY CHANGES

As HCFA works toward implementation of outpatient PPS, there are several areas of concern we have with the apparent direction in which the agency seems to be headed. Specifically:

Provider-based outpatient facilities: Hospitals are no longer just buildings with four walls. Today, more than ever, advances in science and technology have allowed hospitals to reach out into their communities to bring care where it is needed. This is especially true of outpatient services. In community after community across America, hospitals are working with others in their communities to bring care where it is needed.

Unfortunately, HCFA threatens this expansion of care by adding too-narrow requirements for determining what entities can be considered hospital outpatient departments. While there are reasonable and important distinctions between hospital outpatient departments and physician offices, HCFA's requirement for state licensure is arbitrarily biased against providers in states where licensure does not even exist to cover off-campus facilities. Conditions of participation or accreditation should be used where licensure is not available. Moreover, the proposed requirement that Medicare should mirror how other payers view these facilities is one-sided, ignoring contractual arrangements between hospitals and private insurers that offset the lack of a facility fee. These requirements will discourage hospitals and health systems from reaching out and bringing high-quality health care to underserved areas of their communities.

Volume cap: HCFA proposes to reduce future payment updates if Medicare payments for hospital outpatient services exceed the agency's projections. If this proposal is implemented, hospitals would be penalized for adopting new technologies and treatments that increase the volume of outpatient services while also enhancing the lives and comfort of beneficiaries.

The President's Medicare reform proposal indicates that the administration is considering delaying implementation of this proposal. While we commend the adminis-

tration, just a delay of bad policy is not sufficient. We strongly urge HCFA to exercise its option under the BBA to drop this provision altogether. Doing so will ensure that beneficiaries have continued access to new treatments and technologies in the outpatient setting.

Accuracy of data: We are extremely concerned about the data with which HCFA is calculating its payment rates under outpatient PPS. For example, HCFA estimated that Henry Ford Health System would see an increase of almost \$1 million in outpatient payments under PPS. However, our own analysis identified several discrepancies in HCFA's estimates. In fact, we calculate that Henry Ford will actually see a decrease in payments of \$9.6 million, or 21 percent of our total outpatient revenue. If a hospital like ours, which was expected to see a slight increase in payments, actually experiences a 21 percent reduction, what will happen to those many hospitals projected to experience a 30 percent loss?

The BBA requires that HCFA use a reliable payment methodology. The margin of error we have found clearly indicates HCFA's proposal does not meet this requirement. This is a key reason why a payment "floor" is needed, such as Rep. Foley's bill (H.R. 2241), which I mentioned earlier in this testimony. Such a floor would protect hospitals from catastrophic losses while HCFA makes the coding/reporting changes needed to provide HCFA with accurate information so the agency can in turn provide more accurate projections of the effects of outpatient PPS.

One way to refine the data is to create a panel of hospital outpatient administrators and government staff who can work together to review the classifications.

Chemotherapy: The AHA believes that there are serious problems with the data HCFA is using to determine payment for chemotherapy services. As a transitional payment methodology, the AHA recommends that HCFA carve out the costs for chemotherapy and chemotherapeutic agents and pay on a reasonable cost basis until the agency fixes the underlying coding problems, collects new data, and proposes new groups or rates. The results would then be included in a subsequent proposed rule. Otherwise, hospitals may be forced to close their cancer centers rather than provide lower quality or inappropriate care.

In addition, HCFA's proposal to classify new agents in the lowest cost group does not reflect what we expect in the future for drug costs. According to the Bureau of Economic Analysis and other sources, most of the new drugs—especially new genetically engineered drugs—are more costly than prior drugs. Clearly, this proposal would penalize hospitals for using new pharmaceuticals. Moreover, it is incumbent on the agency to get the information it needs on drug prices to ensure that it can classify new drugs, or any new technology, into the most appropriate group from the standpoint of both clinical coherence and resource use. The AHA opposes HCFA's proposal to place new agents in the lowest payment group.

OPPOSITION TO THE 5.7 PERCENT CUT

As mentioned earlier, once the new outpatient PPS system is implemented, HCFA plans to reduce hospital outpatient payments by another 5.7 percent. This means that, on top of the \$9 billion in five-year outpatient payment cuts already included in the BBA, hospitals would suffer another cut of \$900 million annually. This is contrary to the wishes of more than 255 members of the House, and 77 members of the Senate, who signed recent letters to HCFA opposing this arbitrary, unfair, and uncalled for cut.

According to the congressional letter, HCFA's proposal decision to cut an additional \$900 million from Medicare outpatient payments is "inconsistent with Congress' intent," and would be "inappropriate and unwise." The AHA believes that HCFA has the flexibility to interpret the law correctly, so that the proposed payment system does not extract another \$900 million from hospitals.

CONCLUSION

The vision of America's hospitals and health systems is "a society of healthy communities." High-quality outpatient care is a cornerstone of this vision, as more and more hospitals break down their figurative four walls and reach into the community to provide care where and when it is needed. The scientific and technological advances that allow us to do this reflect the kind of innovation that will serve Americans well into the next century.

In order for hospitals and health systems to continue providing high-quality outpatient care, it is critical that outpatient PPS be implemented carefully. We look forward to working with Congress and HCFA to fix the problems that I have outlined.

Mr. BILIRAKIS. Thank you, Mr. Warden. Hospitals in Florida certainly are closing left and right and others are threatening to close. I know those that we do not know about Mr. Koon, who is sitting behind you, tells us about that.

So we hear you all, believe me. You have had the unfortunate problem of sitting in the audience since 10 this morning listening to all the other witnesses, so you know that we have basically heard it all, I think.

Dr. Corlin, you stated the largest shortcoming in SGR payments due to incorrect estimates are felt in Florida.

Mr. CORLIN. Yes, sir.

Mr. BILIRAKIS. Now HCFA claims that it does not have the legal authority to correct the estimate from year to year. You say—I think this is your word—incredulous. You say that that is incredulous.

I wonder if you could have your legal experts at AMA substantiate your position for the record. We are meeting, as Mr. Brown and others know, we are all meeting together with Mr. Hash hopefully next week and staffs are meeting later this week, although I do not know with the hurricane coming up this way, I am not sure about that. By the way, this is the proposed path. It's not going to hit Michigan.

But in any case, I do not know about the staffs' meeting later this week, I guess is what I mean. But we would like to have that information in case any problem develops. I mean as much as they can make administrative fixes, it would be so much easier for the overall effort.

So if you could have your legal people furnish that to us, you say it is incredulous. I assume that that is based on probably what your legal people have said to you?

Mr. CORLIN. Yes. I obviously do not have that information on hand now.

Mr. BILIRAKIS. No, of course.

Mr. CORLIN. I will see to it that the responses to your questions are faxed to both you and Mr. Brown before the end of the week.

Mr. BILIRAKIS. Okay, great. And of course we will have plenty of questions for all of you in writing and we would ask for you to respond to them.

As I said earlier, we hear you and I hope we are getting the message across to you that we are going to try to do something.

Now Miss Roberts, I am just going to use you as a representative of all the provider organizations, not only those that are here but some who are not. You stated that there were 2,486 home health agency closures. I do not know over what period of time these took place. We do know that in the decade prior to 1997 the number of home health agencies almost doubled to 10,524, according to GAO.

Now I am making these points just to show you all that everybody was imploring upon us to do everything we could, to basically try to save Medicare and that sort of thing. And you know this is what we were faced with. And unfortunately, what we did was we overdid it and we admit that unintended consequences took place.

GAO told us that in 1989 there was an average of 27 visits per home health patient. By 1993, just 4 years later, the average had become 59 visits, a 118 percent increase since 1989. By 1996 the

average had risen to 79 visits, a further 34 percent increase. 1997 data indicated there was a drop back to 72, but still a 167 percent increase above the 1989 level.

So this is the sort of thing, and obviously home health care is not the only problem out there but this is the sort of thing we were faced with in terms of trying to draft up that legislation. And, as I said earlier, this is big stuff. It was bigness and we are an ivory tower and we try to do the best that we can. In spite of the fact that we have 2 or 3 doctors on this committee now, which is something we did not have before, we did the best we could but we messed up in many areas and we are trying to fix it now.

I do not know that I really have any more questions. I do want to thank you for being here and to apologize for the long delay.

With Mr. Brown's permission I would like to recognize Mr. Dingell to inquire. Would you like to inquire?

Mr. DINGELL. Yes, if it is my turn, Mr. Chairman.

Mr. BILIRAKIS. Mr. Brown yields to you.

Mr. DINGELL. Thank you. Mr. Brown, I thank you.

Mr. Warden, let's talk about the situation in our area in Michigan. We are liable to lose four hospitals back there in the very immediate future; isn't that so?

Mr. WARDEN. That is correct.

Mr. DINGELL. That will come about in good part because of the level of payments both for Medicare, Medicaid and other Federal services; is that right?

Mr. WARDEN. Those are the primary reasons, yes, sir.

Mr. DINGELL. That could come as early, say, as January?

Mr. WARDEN. All of them will happen between January and July of the year 2000.

Mr. DINGELL. What would the consequences be to the patient population back there in terms of what that would do? Significantly, the Medicare-Medicaid population would suffer significant loss of opportunity to get good treatment. It would mean also further declines in the level of service available to them. It would also mean waits and things of that kind. It would mean that all of the remaining hospitals would essentially be functioning at or above their level of capacity; isn't that so?

Mr. WARDEN. That is correct. Actually in the case of the hospital in the city of Detroit, it would basically mean that there is no hospital on the east side of Detroit if that hospital closes. Closing with that will be several clinics that are operated by that institution. It will mean that the patients are going to have to go further to receive care. It will mean that more care will be delivered in the emergency room, which means delays in treatment, and it also will mean that it will have an impact, I think, upon the other services that are available in those communities because a lot of the other community services have been backed up by the hospitals.

In the case of the other institutions that are threatened, it will mean that in most cases people will have to go further to get care and there will be some physicians who are somewhat displaced because they have been practicing in those institutions and will have to find another venue.

Most importantly, it is going to mean delays in seeking care and the ability to get to the place to have care. One of the big problems

Mr. BURR. From a policy standpoint, if we were to pass a law that said you can never use the new technology until there is a replacement for the new technology and then you can use that technology that was replaced, would we be accused of not being concerned with the quality of the care supplied to individuals?

Mr. HOLVECK. I think you would.

Mr. BURR. Under that scenario, aren't we using antiquated drugs or devices to supply service?

Mr. HOLVECK. Well, I think the ability to use new technology I think is going to suffer in the interim.

Mr. BURR. What is the determining factor based upon? As I understand it, the FDA determines the safety and efficacy of the drug or device.

Mr. HOLVECK. That is correct.

Mr. BURR. What takes 3 years for us to incorporate that into the Medicare system?

Mr. HOLVECK. HCFA tracks data and sees what the incremental cost is that would allow them to shift a cost in the DRG.

Mr. BURR. So their determination is not based upon the effectiveness or the quality of care? The safety and efficacy have already been determined.

Mr. HOLVECK. That is correct. It is the incremental cost that would change the reimbursement rate.

Mr. BURR. 100 percent cost?

Mr. HOLVECK. Yes.

Mr. BURR. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Brown?

Mr. BROWN. Mr. Holveck, let's talk about costs for a moment. I visited this week, Monday morning actually, with Lorain Community Partners Hospital, the result of two hospitals that have merged, a public hospital and a Catholic hospital that have merged in the city of Lorain, where I live on Lake Erie in Ohio, a city of about 75,000 people, high numbers of low-income residents. This hospital has talked about a lot of the problems that Ms. Rapp mentioned and that all of you have mentioned.

One of the problems, one of the largest and most rapid increases in terms of costs is the cost of drugs. If Medicare reimbursement would continue to fall there would be pressure on the drug manufacturers, I assume, to reduce the prices that they charge hospitals. In your view, do drug manufacturers have in flexibility in reducing prices to hospitals?

Mr. HOLVECK. I refer to the fact that I am in biotechnology and I do not know that I have an insight on classical pharmaceutical drug development, but I think that from my vantage point, running a company, it is a very costly operation. We are 20 years in existence and only went profitable 2 years ago after \$1.5 billion of public funding went into it.

So when you talk about our abilities or abilities to reduce costs, I think you have to understand the infrastructure that we have to pay for up front in order to get that growth and get those investors to support our research.

So I can speak for only my particular industry, if you would, biotechnology, or my particular company. I do not know that there is

a lot of latitude certainly in my experience in terms of just arbitrarily reducing costs of a drug.

Mr. BROWN. Miss Roberts, I was struck by some of the differences between your testimony and the testimony of the General Accounting Office in the prior panel. You both agree that many home health care agencies have closed. It has happened in probably every district represented up here, I would guess. And you both agree that payments have decreased to home health agencies since the Balanced Budget Act of 1997.

You also heard the numbers mentioned earlier by the chairman about the growth but GAO, where you and they parted, GAO did not find conclusive evidence that seniors' access to home health services had suffered as a result. That is their evidence.

Anecdotally perhaps, in one county in my district a fairly large home health agency closed but others seemed to pick up the patient load that they had.

What gives here? GAO is saying—help me understand this—GAO is saying that seniors' access has not been compromised. You are saying it has.

Ms. ROBERTS. The number of beneficiaries receiving services across the country are 15 percent less than they were pre-balanced budget. Our State is greater than that.

While certainly there has been consolidation of agencies, which always makes the number of agencies that have actually closed a moving target because, as you mentioned, agencies come together and they should have the same degree of capacity, but what we do know is that agencies do not have the same degree of reserve.

I talk about just-in-time staffing. We are literally faced with agencies staffing themselves to the bare bones. As such, when unexpected increases in volume or patients needing greater than the average degree of services are presented, they are, in fact, not accepted by the organization. They literally do not have the staff or the resources to provide that care.

We in the State of Rhode Island are tracking how many extra days people are staying in hospitals or long-term care facilities because they cannot get access to home care services. The cost-benefits seem very obvious but, by the same token, we have not been able to successfully make change on this policy.

Mr. BROWN. The 15 percent figure I would like to explore now. GAO surely has access to that figure. Why would they claim that seniors' access to home health services has not suffered?

Ms. ROBERTS. I think one of the ongoing issues which has been discussed numerous times throughout today is data, and what I am talking about is real-time data, real stories that are happening in our communities. I think as HCFA presents their data, the information they present is consistently dated. Report after report that they cite goes back to 1998 when in many instances we were just beginning to feel the first impact of all of this.

So I think there is a difference from being in the community, being in a real-life situation versus going on old information.

Mr. BROWN. One last question. So what happens to those 15 percent that you say are underserved? Do they stay in hospitals a day longer, a week longer? Are they home with no assistance? Do they have to call on neighbors and friends and relatives that may or

may not exist in each specific case? Do they get sicker and die sooner? What has happened to them?

Ms. ROBERTS. I do not think there is any one single thing that happens to all those individuals. I certainly can provide information very specific from our own State. The people are staying in hospitals, staying in long-term care facilities. They are waiting several days at home without care. That is very apparent.

Their general condition, I would suggest, would deteriorate as they wait. I do not know that I could give you any more specifics, though, in terms of what the outcomes are.

Mr. BROWN. Are you willing to claim that because they stay in hospitals longer, because they get sicker and need more Medicare services separate from home care, particularly those two things, do you claim that it costs Medicare more money in the end to do this?

Ms. ROBERTS. Absolutely.

Mr. BROWN. Do you have evidence of that, other than that might follow some logic?

Ms. ROBERTS. I think it is very simple. If you look at what the daily hospital rate is, for example, an average rate in the State of Rhode Island is \$700 a day. If, in fact, someone could go home and have a home health visit at less than \$85 a day, it seems to be evident that, in fact, that—

Mr. BROWN. If you want to play those numbers though, when you look at the incredibly rapid growth of home care, as the chairman pointed out in his statement earlier, and the larger and larger percentage of the Medicare budget that home care has taken, has used, has consumed, and, at the same time, you look at the growth in hospital costs, if home care had not grown so fast, hospital costs would have even gone more through the roof, and nursing home costs?

Ms. ROBERTS. Well, certainly some people would draw those conclusions.

Mr. BROWN. Would you?

Ms. ROBERTS. I think there is no question that prior to the balanced budget there did need to be some changes to many of the Medicare benefits, home health included. There was a deliberate intention out to move patients out of the hospital to the community setting. In fact, the home care community responded to that and the industry grew, perhaps somewhat unchecked—I would not dispute that. But again, there was some cost-shifting that happened from inpatient care to home care service.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Miss Rapp, before I go to Mr. Bryant, were you asked whether Medigap covers payment for therapy services once the cap is met?

Ms. RAPP. It does not.

Mr. BILIRAKIS. It does not. None of the Medigap plans do?

Ms. RAPP. No.

Mr. BILIRAKIS. Thank you.

Mr. Bryant will inquire.

Mr. BRYANT. Thank you.

Mr. Warden, let me open quickly with you. As the president of what I understand to be a major health care facility, a hospital there in Detroit, do you have any comments on Ms. Roberts' ques-

tion? I know in your statement you made a comment about home health care perhaps needing more payments. Do you have a comment on this GAO issue of access?

Mr. WARDEN. I would only say that in an integrated system like our organization is, which has home health as an integral part of what we do, home health is a strategy, very much a strategy for getting patients out of the hospital and reducing costs, the overall cost of caring for that patient in the episode of illness. It really is an expense in our organization, not a revenue-generator.

So our perspective on home health, even though we have a huge home health operation, is a little bit different than it is in a lot of other organizations.

Mr. BRYANT. Certainly you view it not as a competitor but as a group that works together—

Mr. WARDEN. No, we view it as very much an important part of the continuum of care. We use outside agencies as well as our own agency, but we view it as part of a continuum and try to provide the care at the right place and the right time.

Mr. BRYANT. You have testified on behalf of a very large urban hospital but are you aware of Michigan having rural hospitals that, because of the BBA, are facing extinction?

Mr. WARDEN. Yes.

Mr. BRYANT. In essence, the same problem only multiplied greatly because of—

Mr. WARDEN. Many of them are the sole provider in their community. I think one of the reasons I used the example is I think the problems for rural hospitals are equally as important or maybe more important in some cases than the challenges that we are facing in urban teaching hospitals.

Mr. BRYANT. Now that you mention urban teaching hospitals, my other question to you was I am not sure that has been discussed a great deal today but again I had people come up yesterday and talk to me about how important that was and how we must ensure that more than adequate funding is there for our teaching hospitals and your institution is a teaching hospital?

Mr. WARDEN. Yes, a very big teaching hospital. As a matter of fact, of the \$200 plus million that I described for a 5-year period, the largest ticket item is indirect medical education.

Mr. BRYANT. Dr. Corlin, from the perspective of a practicing physician, could you comment and on behalf of the AMA on this teaching hospital issue and the need to fund it?

Mr. CORLIN. From the standpoint of the AMA and also our group is on staff at a major teaching hospital, UCLA, and they are being terribly impacted. It is multi-factorial.

Part of the problem has been that the teaching hospitals have come to rely enormously on the money that comes to them through the Medicare system and directly from other sources for teaching. In a way, these cut-backs are cuts of their last source of revenue because unfortunately, and I know this goes beyond the scope of this hearing but I know that Mr. Warden, I am sure, will agree with it, unfortunately, the private insurance companies, the for-profit HMOs and others, do not contribute their fair share to provide for the graduate medical education burden.

...and they are coming back left, right and center.

...and I am not that—it is my personal belief that ... will cause substantial reduction in the availability of graduate medical education positions because of the inability of hospitals to maintain them.

Mr. BRYANT. Thank you, Mr. Chairman.

Before I yield back my nontime, I want to thank the panel for their patience. I know they have been here all day. Thank you.

Mr. BILIRAKIS. Thank you for yielding back your nontime.

Without objection, Mr. Burr has a quick one question.

Mrs. CUBIN. Mr. Chairman, I am back. I have two questions. I will make it very quick and then I will yield the balance of my time to Mr. Burr.

Mr. BILIRAKIS. The gentlelady is recognized.

Mrs. CUBIN. Dr. Corlin, two things. You stated that Florida has lost the most money due to the BBA and I absolutely would expect that to be so because there are more senior citizens there.

Do you have a per capita figure on that? And if you do not, maybe you could get one? If not, maybe I can get one.

Mr. CORLIN. I do not have a per capita figure. We took the \$3 billion total loss; approximately 9.6 percent of the Medicare population resides in Florida, and that is how we arrived at that figure.

With regard to Wyoming, the loss in Wyoming is probably in the range of between \$3 million and \$4 million, which is probably proportionately an enormous amount for the State of Wyoming.

Mrs. CUBIN. That is correct. It truly is.

Now the chairman said that he did not want this hearing to turn into Medicare Choice, and I do not, either, but I have a question about the fairness gap that has been discussed. So I am just going to ask you this one question, Dr. Corlin, if you do not mind, and then I will yield to Mr. Burr.

Under the Balanced Budget Act, Medicare Plus Choice payments are no longer based entirely on Medicare fee-for-service rates and as a result, the health plans say that a few years from now most Medicare patients will live in areas where Medicare payments to managed care plans are about \$1,000 less than fee-for-service payments. This is what is being called the fairness gap.

And saying that Medicare Plus Choice payments should not be allowed to fall below 91 percent of fee-for-services in any county, what is your representative reaction to that proposal?

Mr. CORLIN. Well, that is an issue which cuts both ways. The ... about a third of the counties in the country are ... to managed care organization for those of us who take care of fee-

... say in my own practice, we do ... the balance ...

I am a bit rankled by their statements, particularly given the fact that many of the for-profit managed care organizations choose not to contribute to graduate medical education or to subsidizing uncompensated care for the poor. They do not take risk, yet they make profit, which in my little educational background about what capitalism is all about, making profit without taking risk is a rather unique situation.

And what is more than that, despite the fact that they are being guaranteed 2 percent increases in reimbursement, many of them are dropping out of the Medicare program. I would not consider dropping out of the Medicare program. I consider it an obligation that I have as a professional, to take care of anybody who comes into my office.

As of right now, the payment that we get is probably about 50 percent of our billing. If it goes down, it is going to hurt. But I am not going to stop, like some of the HMOs are going to stop. If they want to talk about fairness, I am willing to sit here all day long and talk to them about fairness gaps.

Let's have one of the CEOs of the biggest 25 HMOs in the country, whose average income last year was \$21 million, let's have one of those 25 people come here and I am willing to debate fairness gap with them all day long.

Mrs. CUBIN. Thank you.

Mr. BURR. I thank the gentlelady for yielding. I certainly will not try to determine who can holler the loudest.

Dr. Corlin, let me just go to the heart of one thing that you mentioned, and that was technology. I would ask you how many times a day for a physician does a patient who walks in the door who you are treating ask you about a particular procedure or a particular medication versus you mentioning it?

Mr. CORLIN. Within the past 2 or 3 years, Mr. Burr, that is happening increasingly frequently. In my case it is more with medications than procedures. I can think of treatment for two things and I think one of them may be the medication Mr. Holveck was referring to, Enfleximed, which is a new medication for Crohn's disease, and the other is treatment for hepatitis C.

An increasing number of patients come into my office for a consultation with a difficult problem with either of those two diseases, and after I have finished taking their history and examining them and I begin to talk about treatment options with them. The first thing they do is open their folder of everything that they have pulled down off the web on the treatment of one of those two conditions and embarrassingly, sometimes they are ahead of me on it.

So I find that very good. We are seeing a better informed group of patients. Now all the information is not valid, to be sure, but a lot of it is and it is a sign, I believe, that the patients are taking more of—this may sound foolish—but a personal interest. Since they will have the feeling that they helped develop the treatment plan, I think they will be more compliant with the treatment. With a chronic disease such as that, that is a crucial point.

Mr. BURR. Given that there is a significant difference in where we are on health care based upon all parties who have an opportunity to testify, just one closing comment.

It seems irrational a lot of times until you realize that we are in a system where the two ends of the spectrum are like this. Every day at the NIH somebody wakes up, goes to work with one thing in mind: How can I take all the discoveries that were made yesterday and put them on the Internet so every researcher in the world can start at that point with that day's work?

And at the FDA somebody wakes up every day and goes to work with one thought in mind: How can I make sure that no breakthrough from yesterday ever gets on the Internet until we have approved the safety and efficacy? Those are the two different ends of the spectrum and I think that tells you how we can have so many different policy debates as it relates to health care, as well.

I thank the chairman. I also thank this panel for lasting out the other members of the committee.

Mr. BILIRAKIS. Yes, I certainly endorse that. It is always terrible when you are the last, I feel, but you have done a terrific job and we appreciate it very much. You have been very helpful and honestly, we are going to do the best we possibly can. Thank you very much.

Again you will respond to written questions.

[Whereupon, at 3:55 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

AMERICAN MEDICAL GROUP ASSOCIATION

September 14, 1999

Chairman MICHAEL BILIRAKIS
Subcommittee on Health and Environment
2125 Rayburn
Washington, DC 20515

DEAR CHAIRMAN BILIRAKIS: The American Medical Group Association represents approximately 45,000 physicians in more than 250 medical groups from across 40 states. AMGA members are among the largest and most prestigious medical groups in the country and include such renowned organizations as the Mayo Foundation, the Palo Alto Medical Foundation, the Lahey Clinic, the Henry Ford Health System, the Cleveland Clinic, and the Permanente Federation, Inc. AMGA's mission is to shape the health care environment by advancing high quality, cost-effective, patient-centered and physician-directed health care.

The Balanced Budget Act of 1997 (BBA) was the most significant reform of the Medicare program since its inception in 1965. The BBA encompasses over 300 changes that have had, and continue to have, significant implications and consequences for medical groups and the patients we serve. Multi-specialty medical groups are unique in that are comprehensively involved in all aspects of health care delivery affected by the Balanced Budget Act: physician services, inpatient and outpatient hospital care, Medicare+Choice health plans, skilled nursing facilities, teaching hospitals, and home health care. Consequently, multi-specialty groups have sustained, and continue to sustain, dramatic revenue reductions which interfere with capital budgeting and patient care.

AMGA understands the need to eliminate unnecessary and wasteful services and inefficiencies. However, the reimbursement reductions imposed in BBA '97 are having a significant negative impact on the ability of medical group practices to continue to deliver quality care to beneficiaries and are threatening the financial viability of many groups. AMGA members are struggling to make up for the shortfalls caused by the BBA, yet, rather than compromise the quality of services they provide, groups are finding it necessary to cut back on beneficial services and uncompensated care. For your review, we have attached a few real examples of the estimated net revenue impact of specific items in the BBA 97.

It is our understanding that this fall Congress is likely to consider a package that would provide BBA relief to providers who have been severely hampered in their ability to serve Medicare patients. Medical groups need both administrative and legislative remedies if they are going to continue delivering quality care. Relief from the Balanced Budget Act should include:

- Relief from reductions for teaching hospitals and academic medical centers. BBA limits payments for IME, interfering with teaching hospitals' ability to provide quality care to the poorest and sickest individuals. AMGA supports legislation introduced by Rep. Charles Rangel (H.R. 1785) and Senators Moynihan and Kerrey (S. 1023) that would freeze IME payments at current levels and prevent future scheduled BBA cuts.
- Repeal the patient transfer provision. Under the expanded transfer definition, the government pays less for the shorter stay but does not increase payment for longer-stay patients. AMGA supports legislation proposed by Senator Grassley (S. 37) and Rep. Jim Nussle (H.R. 405) which would repeal this provision.
- Fix the way Medicare pays Medicare+Choice plans by:
 - Requiring HCFA to implement the risk adjustment process on a budget neutral basis. The "risk adjustment" process was intended to distribute funds based on the health status of M+C enrollees, however, HCFA has proposed a model that would impose deep spending cuts in the M+C program. AMGA supports H.R. 2419, the "Medicare+Choice Risk Adjustment Amendments of 1999," introduced by Congressman Michael Bilirakis.
 - Speed up implementation of the risk adjustment mechanism, permitted that it uses a reliable database that takes into account the beneficiary's health status and medical costs. Many of our medical groups care for a disproportionate number of the sicker Medicare population and have faced a sharp reduction in Medicare payments.
- Require HCFA to modify the Sustainable Growth Rate (SGR) expenditure target. Currently, there are significant flaws in the formula that is used to calculate the annual payment update for physician services. Absent significant modifications in the SGR, physicians face payment constraints that are far more severe than Congress intended.
- Delay implementation of the prospective payment system for outpatient departments so that HCFA can address and amend the proposed rule. The proposed rule has numerous problems and would severely impact medical groups across the country. As proposed, the rule does not recognize that integrated systems have moved many services to ambulatory sites. We support legislation introduced by Senator Jeffords (S. 1263) and Rep. Mark Foley (H.R. 2441) that would provide for a transition period and limit payments reductions over three years.
- Restore the budget neutrality on the new prospective payment system's reimbursement methodology. The 5.7% across the board reduction in payment to outpatient departments imposes an \$850 million per year reduction in payment to hospitals that was not intended by Congress in the BBA. Congress intended that payments to hospitals should remain budget neutral under the new PPS system. We support the steps taken by Reps. Johnson and Cardin, and Senators Cochran, Kerry, and Rockefeller urging HCFA to restore the budget neutrality.

In addition, AMGA commends President Clinton for taking the steps to introduce a Medicare reform proposal that seeks to modernize the program, introduce private sector innovations, and help seniors pay for prescription drugs. In particular, we strongly support the creation of a demonstration project of bonus payments for physician group practices who reduce excessive use of services and demonstrate positive medical outcomes for their patients. Based on our members' experience, medical group practices are leading the way to cost-effective, high quality health care through integrated financing and delivery of medical services. A shared commitment and an underlying patient care mission by all involved have produced superior results in quality health care service and satisfaction for both patients and providers. Through organized delivery systems, providers save time, money, and resources, and improve patient care.

At the same time, we are disappointed that the President's proposal continues the pattern of cutting payments to providers as a way to maintain Medicare solvency. President Clinton's Medicare reform would cost hospitals and health plans \$70 billion over 10 years. The potential for additional Medicare cuts to medical groups will be disastrous because, as integrated practices, they carry the burden of the full scope of reductions.

While we recognize the need to eliminate inefficiencies and wasteful services, the Federal government cannot finance and expand the Medicare system by cutting provider reimbursements. The President's proposed reductions come on the heels of Medicare spending reductions contained in the Balanced Budget Act of 1997, and will reduce our ability to provide quality services that the elderly depend on. While the President's establishment of a \$7.5 billion provider set-aside fund appears to recognize that the BBA 97 reductions were too harsh, this funding level is insufficient to address reimbursement inadequacies and does little to ensure that Medicare

beneficiaries will continue to have stable access to health care providers. More importantly, the \$7.5 billion would result in battles among the provider community to determine who is most worthy of relief.

Rather than implement further reductions at the expense of health care delivery, Congress needs to do two things: First, Congress needs to fix the unintended consequences of the Balanced Budget Act. This will ensure that Medicare beneficiaries will continue to receive quality and cost-effective care from providers and medical groups. Second, if solvency of the Medicare program is to be sustained, Congress needs to fundamentally restructure and modernize the Medicare program. Such a system should be based on the principles of patient choice, competition, innovation, a defined role for the government, and should adopt marketplace innovations. Continuing to reduce provider reimbursements as a part of reform is not a viable option.

We appreciate your taking our views into consideration. We look forward to working with Congress on Medicare reform and adjustments to the Balanced Budget Act of 1997. Please do not hesitate to contact AMGA if you have any questions or concerns.

Sincerely,

DONALD W. FISHER, PH.D., CAE
Chief Executive Officer

Cc: Majority Leader Trent Lott, Minority Leader Tom Daschle, Speaker Dennis Hastert, Minority Leader Dick Gephardt, Majority Leader Dick Armey, Senator William V. Roth, Jr., Senator Daniel Patrick Moynihan, Congressman Tom Bliley, Congressman Bill Archer, Congressman Bill Thomas, Congressman Charles Rangel, Congressman Fortney Pete Stark, Senate Finance Committee, Commerce Committee, Ways and Means Committee, Administrator Nancy-Ann DeParle, Mr. Christopher Jennings, and Dr. Robert Berenson.

Mayo Foundation—Rochester, Jacksonville, and Scottsdale

(in millions of dollars)

BBA Reductions	1998	1999	2000	2001	2002	2003	Total
Reduction to IME payment Rate	6.4	13.9	20.5	26.5	28.5	30.7	120.1
PPS-exempt unit TEFRA rates	—	1.0	1.0	0.9	0.8	0.7	4.3
Reduction to Federal capital Payments	5.1	5.6	6.0	6.5	6.7	6.8	31.7
Transfer DRGs	0.6	2.5	2.5	2.5	2.5	2.5	12.6
Outpatient PPS (assume 5% reduction)	0.3	0.7	0.7	0.7	0.7	0.7	3.5
Outpatient formula-driven overpayments	1.1	1.7	1.8	1.9	2.0	2.1	9.4
Eliminate IME payment on outliers	3.4	3.8	3.6	3.6	3.8	4.1	19.0
SNF prospective payment	—	3.0	6.0	9.0	12.0	12.0	42.0
Reduction to bad debts	—	0.1	0.1	0.1	0.1	0.1	0.4
HHA reduction to limits and PPS0.5	0.5	0.5	0.5	0.5	0.5	0.5	2.5
Medicare Part B physician fee schedule	—	3.0	6.0	9.0	12.0	12.0	42.0
Total Reductions	18.3	35.6	45.5	54.9	68.4	63.8	259.3

Henry Ford Health System—Detroit, MI

(in millions of dollars)

BBA Reductions	1998	1999	2000	2001	2002	Total
PPS-Hospital Payment Update	5.2	8.9	12.5	14.7	17.0	58.3
IME Adjustments	3.2	5.7	8.2	10.7	10.7	38.5
Capital Payment for PPS Hospitals	3.3	3.3	3.3	3.3	3.3	16.5
Transfer DRG Provision	—	3.1	3.1	3.1	3.1	12.4
Disproportionate Share Payments	0.1	0.2	0.2	0.3	0.4	1.2
Bad Debt Payments	0.5	0.8	0.9	0.9	0.9	4.0
Formula Driver Overpayments	2.9	2.9	2.9	2.9	2.9	14.5
Outpatient PPS	—	—	4.8	9.6	9.6	24.0
Physicians Single Conversion Factor	1.0	1.0	1.0	1.0	1.0	5.0
Physician Practice Expense RVUs	—	0.6	1.0	1.4	1.8	4.8
Home Health Interim Payment System	1.0	—	—	—	—	1.0
Sustainable Growth	—	1.2	1.7	1.2	1.2	5.3
HMO 2% Cap	2.2	4.6	TBD	TBD	TBD	6.8+
Risk Adjusting Scheme	N/A	N/A	TBD	TBD	TBD	TBD
User Fees	525,000	620,000	651,000	684,000	718,000	3.2

Henry Ford Health System—Detroit, MI—Continued
(in millions of dollars)

BBA Reductions	1998	1999	2000	2001	2002	Total
Total Reduction	19.9	32.9	39.3	49.8	52.6	195.5+

Lahey Clinic—Burlington, MA

BBA Cuts	1998	1999	2000	2001	2002	Total
PPS Hospital Updates	1,295,081	2,466,203	3,379,178	3,964,511	4,578,043	15,683,016
Formula Driven Overpayment	850,000	850,000	850,000	850,000	850,000	4,250,000
IME	1,322,000	2,555,000	3,266,000	4,199,000	4,199,000	15,241,000
IME Managed Care	562,500	1,500,000	2,200,000	2,900,000	3,480,000	10,642,500
Transfer Policy	—	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
APC	—	—	1,000,000	2,000,000	2,000,000	5,000,000
Single Conversion Factor	750,000	1,000,000	1,000,000	1,000,000	1,000,000	4,750,000
Resource-Based Practice Expense						
RVU	—	300,000	700,000	1,100,000	1,500,000	3,600,000
Total Reduction	3,854,581	6,371,203	8,985,178	11,213,511	11,847,843	41,881,519

AMERICAN MEDICAL GROUP ASSOCIATION
July 30, 1999

Health Care Financing Administration
Department of Health and Human Services
Room 309-G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: HCFA-1005-P

On behalf of the American Medical Group Association, I appreciate the opportunity to provide comments on the proposed rule that establishes a prospective payment (PPS) system for Medicare outpatient services, published September 8, 1998, in the Federal Register.

AMGA represents over 250 physician-owned and managed group practices and multi-specialty medical groups. In direct response to market forces, physicians are increasingly joining or forming larger multi-specialty groups, and integrating with other health care entities such as hospitals, ambulatory care facilities, and insurers. The goal of group practices is to create seamless delivery systems to offer the full continuum of care under the same corporate umbrella. Many of our group practices are highly integrated health care delivery systems, with multiple facilities, programs and locations.

We are very concerned that the proposed rule does not recognize an integrated delivery system organizational model in which there are multiple parts delivering medical care to a population. The rule appears to be modeled for smaller, less-integrated entities that are organized around one or two free-standing hospitals with ambulatory services directly flowing from the activities of a single hospital and private practice physicians. The proposed rule does not take into account the kinds of organizations structures that are common to larger delivery systems, such as the Palo Alto Medical Foundation, the Cleveland Clinic Foundation, and the Henry Ford Health System. We are concerned that the proposed rule, as drafted, will limit beneficial integration, will lead to unfair payment, and will adversely impact beneficiary access to service and quality of care.

In a large integrated delivery system specialized administrative and clinical resources such as in-patient hospital, ambulatory care, home health care, durable medical equipment, etc. are organized under one overall umbrella, to provide seamless medical care to a community population. Under the Proposed Rule, the "main provider" which is likely to be a hospital, is required to exercise ultimate, total control over all the other parts of a system of care. However, in an integrated delivery system, it is not always the hospital which exercises such control but rather the system as a whole. The concept of one hospital with a discrete network of ambulatory sites does not hold in the case of larger systems. The history and culture of the physician group practices is to create coordination and collaboration across sites which results in a further blurring of lines between specialty and primary care, ambula-

tory and inpatient care. The result is a health care system that does not mimic the traditional patterns.

A discussion of some of our main concerns with the proposed rule follows:

Line of Demarcation Between Procedures Covered Only in Inpatient Settings and Those Covered in Outpatient Departments and Ambulatory Surgery Centers

We believe the attempt by HCFA to create a list of exclusively inpatient procedures is in error and should be withdrawn. Medicine is evolving too rapidly for such a list to ever be current. In a cursory review, we identified over 30 procedure codes that are on the inpatient-only list that currently are performed in both settings, depending on patient condition. At best, the list would have the effect of freezing in place inpatient procedures when they may be safely accomplished in the outpatient department or ambulatory surgery center. At worst, it would require care now safely provided in outpatient departments to be returned to the inpatient setting.

This would have the unintended effect of adding costs unnecessarily to the Medicare Program. What is needed is not a rule that prescribes what may or may not be done in inpatient settings, but rather physician discretion, based on the patient's condition, to determine what site of care is most appropriate. Rather than attempting to list all inpatient procedures, patients and the Medicare Program would be better served by establishing some generic criteria related to patient care that would assure that care is safely provided in the appropriate setting. This approach would allow for the needed flexibility for the program to adapt to changing medical practice.

Treatment of Academic Health Centers

We support an education adjustment to payments in hospital outpatient settings. As care is increasingly provided in hospital outpatient departments, so too has residency training with its attendant costs. Your own data show that care costs are more expensive for hospital outpatient departments of academic medical centers. It only makes sense that you honor what your own data analysis has demonstrated.

Definitions and Criteria for Hospital Based Entities

While we understand and support the intent of your effort, we believe the proposed rule is far too administratively complex and detailed. The rules would have the effect of forcing many differing relationships, while provider based, into a single mold, which simply is in conflict with the many real world variations. It is not necessary to have such detailed regulatory requirements in order to define a provider based entity. Below is an itemization of our concerns.

General Reporting Requirements to HCFA—In any acquisition or any material change in status related to provider based, the main provider is required to report to HCFA to obtain approval of provider based status. The main provider would be required to provide "...all information needed for a determination..." A careful reading of the details of this proposed rule find that the amount of information necessary could be exhaustive, depending on the level of "proof" required by the HCFA regional office. This will add a heavy burden to a system that already functions poorly. There are over 10,000 sites which providers believe should be treated as provider-based and which would require review and approval under HCFA's proposal. This number could be much greater depending on HCFA's interpretation of the scope of the rule.

Furthermore, there is no requirement related to timely response by HCFA. If a provider is kept waiting months for approval of a site and is barred from billing until such approval is granted, HCFA is violating the statutory requirement to make timely interim payments. It is not fair to bar providers from billing and receiving payments while waiting for their requests to be approved.

AMGA supports a requirement for a deadline for agency response after which, if not met, the affected parties can move ahead with a presumption of provider based status. Second, we support the creation of a basic form that specifies the types of documentation a provider needs to submit to obtain prior approval so that the provider is not left in the position of having to guess at what is needed and what will be satisfactory. The final rule needs to be extremely clear on precisely what documentation a provider needs to submit to obtain provider-based status for a site. Last, we believe that these provisions should not go into effect until the Agency is prepared to handle the requests. Otherwise, very quickly a significant backlog will result.

Ownership and Control—We believe the ownership and control requirement of 100% ownership by the provider is unduly restrictive. Majority ownership is far more reasonable and relevant to business relationships and still has main provider control.

Administration and Reporting

We believe the requirement that "...reporting relationship to the main provider that is characterized by the same frequency, intensity and level of accountability that exists in the relationship between the main provider and one of its departments..." is unreasonable in that, depending on the particular entity in question, differing levels of reporting are more appropriate. Some department will receive greater attention because of the nature of the services furnished in them or because of problems or changes that arise. The degree of interrelationship on the part of the hospital outpatient department is by definition bound to be more extensive than it will be for a SNF or home health agency or ambulatory surgery center. To require the same detailed reporting level for entities which function in substantially different ways is too restrictive. Again, it gets into "level of proof" arguments which can be subjective and take up an enormous amount of time in attempting to show equivalence. If HCFA maintains some specificity in the final rule, the language should be modified to state that communications between the site and the main provider should be of the same frequency and nature as between the main provider's administration and other similarly situated departments.

We agree with the integration of certain basic functions, such as billing, records, human resources payroll, employee benefit packages, salary structure and purchasing. The integration of these functions, coupled with a simplified reporting requirement should suffice in demonstrating the provider-based relationship. A main provider and a site seeking provider-based status can be administratively integrated yet still maintain its own billing or conduct a number of administrative functions from the site.

Clinical Integration

The clinical integration requirement is too prescriptive. We agree with the general mandate, but disagree with the amount of specificity you have. It does not allow for variation in arrangements in large, complex organizations. First of all, the proposed rule requires the site's medical director to have a "day-to-day" reporting relationship with the medical director of the main provider. However, there is often no need for daily contact and often the medical director works part-time or only a few hours a day. In addition, there is a wide variety in titles and management structure from provider to provider. Second, we do not agree with the decision that the main provider must have an inpatient service in order to monitor and control an outpatient service. As medical science advances and providers become increasingly aware of how to treat patients more efficiently, more services are moving to the outpatient setting, leading to the elimination of the inpatient service. This practice is leading to better care and lower costs. Further, in your language you have a lot of "...we would expect to see..." Either it is a requirement or not.

The "same campus" requirement is archaic. In today's world, providers sprawl across large geographic regions and are not single site. If one meets the other integration requirements, the special requirements for those not on campus are not necessary.

Specific Ambulatory Patient Classification Groups

We are aware that you have received many comments from many specialties and associations concerning particular concerns with the proposed groupings and/or payment adequacy. Below are some particular areas where we have special concern.

APCs

In defense of adopting the APC system, HCFA argues that development of individual payment rates would imply a level of precision that is inappropriate to the quality of available data. While the data on the costs of hospital outpatient services is imperfect, using the APC structure on data of questionable accuracy is not an appropriate solution. AMGA believes that using unreliable and questionable data as the basis of the APC system would simply introduce additional sources of error in the payment system.

If HCFA is committed to using the APCs as the basis of payment for HOPD services, significant restructuring to create more homogeneous groupings will be necessary. Under the proposed rule, many HOPD services have not been assigned to an appropriate APC Group and thus the associated payment rate, which is based on the median costs of all procedures in the APC, is skewed and does not reflect the true costs of the services in that APC. Careful construction of the APCs is critical to the validity of HCFA's proposed payment system. Currently, APCs include very heterogeneous service groups that have payment rates that do not reimburse appropriately for many of the services they include. We strongly urge HCFA to construct APCs so that they are consistent in terms of the packaged services typically

required for each procedure. APCs should be similarly homogeneous with respect to operating and recovery room use, observation care, specialized medical and surgical supplies and blood products.

Even if HCFA succeeds in substantially improving the APCs, some procedures should be individually priced. Under the proposed rule, HCFA packages the costs of Medicare-covered pharmaceuticals in APC groups. AMGA is concerned that packaging all Medicare-covered drugs and biologicals in APC's may jeopardize patient access to innovative and important therapies. However, these APCs are especially undervalued and do not even come close to adequate reimbursement for today's therapies, especially their drug components. Given a substantial disparity between reimbursement and the cost of providing new drugs and therapies, hospitals may opt for less expensive, but less effective treatments to mitigate financial losses. Without adequate means for reimbursing the cost of certain drugs and therapies and an inability to keep pace with the rapid advances in this field, HCFA may unintentionally discourage use of some highly beneficial therapies. AMGA urges HCFA to continue to make separate payments for all Medicare-covered drugs because payment rates are often too low and do not take into account the higher costs of many newer drugs.

Anti-dumping requirements

AMGA opposes the new requirement that hospital outpatient departments, on the main premises of the hospital, comply with the anti-dumping rules. No matter how fully integrated with a hospital an outpatient department may be, it does not provide the full range of services as a hospital, including emergency services. These facilities may be specialized clinics providing limited services, and may be several miles away from its parent hospital.

Physician Supervision

This proposal ignores that some allied health practitioners are permitted by HCFA to practice without physician supervision such as nurse practitioners, physician assistants, etc. HCFA's regulations clearly extend Medicare Part B coverage to these services. It doesn't make sense to impose greater supervision requirements in a provider-based setting than for the same services in other settings. This must be corrected in the final rule. In addition, most partial hospitalization services are furnished by clinical social workers or other licensed personnel who are working well within the scope of their licenses. Here again, the final rule should not require direct physician supervision.

Conclusion

We appreciate the work the Agency has undertaken in an attempt to develop the Ambulatory Patient Classification system for hospital outpatient department and ambulatory surgery center payments. It is a difficult task and the NPRM has served as a useful platform for analysis and debate. However, the proposal is far from a completed product and needs still more analysis prior to implementation. It is for this reason that we recommend that it be re-proposed rather than moving to a final rule, or a final rule with comment. Either of the latter two alternatives will leave us with a badly distorted payment system with unknown consequences for both beneficiaries and providers.

Sincerely,

DONALD W. FISHER, PH.D.
Chief Executive Officer

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The 88,000 members of the American Academy of Family Physicians would like to provide the following comments on the impact of the *Balanced Budget Act of 1997* (BBA) on graduate medical education. Included in this statement are the specific problems with the Act and the Academy's recommendations for solving them. All of the relief the Academy seeks can be achieved in the provisions of the *Graduate Medical Education Technical Amendments Act of 1998* (H.R. 1222), and we urge you to include this bill in any legislation you craft to remedy problems with the BBA. We are pleased that the House Commerce Subcommittee on Health is reviewing how this significant law is impacting cost savings and patient care.

BACKGROUND

The Academy has had a long-standing interest in graduate medical education because of our commitment to a rational physician workforce policy that both discour-

ages an oversupply of physicians, and encourages increased training of those physician specialties in short supply. Our organization has produced and updated regularly a number of policies on physician workforce issues, as well as specific GME recommendations. Recently, the Academy undertook a year long process to revise our physician workforce recommendations with the goal of supporting efforts to ensure that all Americans have access to primary care services; that the needs of underserved rural and urban populations are met; and that evolving managed care delivery systems have an adequate supply of an appropriate mix of primary care physicians.

In addition, the Academy has long been concerned that graduate medical education in the US is currently financed by the Medicare program without sufficient incentives to reduce the oversupply of physicians or ensure appropriate distribution of physicians by geographic location and specialty. Although there are several harmful consequences as the result of this disconnect between Medicare policy and physician workforce needs, one of our primary concerns is the imbalance between primary care and subspecialist physicians in this country.

CHANGES NECESSARY AS A RESULT OF THE BALANCED BUDGET ACT OF 1997

In general, the *Balanced Budget Act of 1997* contains several graduate medical education policies advocated by the Academy for years. The Academy supports a limit on the number of medical residents, and we also support GME payments for training in non-hospital sites and the carve-out of payments to teaching hospitals from the average adjusted per capita cost. However, we have supported these policies in conjunction with specific protections for needed primary care programs. Such protections are absent from the law and regulations. In fact, the only section of the Act that includes an acknowledgment of the importance of primary care training programs is the demonstration project, which allows incentive payments for voluntary reduction in residents. Unfortunately, the Act has had serious consequences for family medicine programs.

Some of the harmful effects of the Act are demonstrated in the following results of a survey of family medicine training programs, which was conducted by the Organizations of Academic Family Medicine.

- 56 percent of family medicine programs responding that were in the process of developing new rural training sites have indicated they will either not implement those plans, or are unsure of their sponsoring institutions' continued support.
- 21 percent of family medicine programs responding report planning to decrease residency slots in the immediate future.
- The majority of those family medicine programs that are planning to decrease residency slots are the sole residency program in a teaching hospital. (This means these family practice programs have no alternative way of achieving growth such as decreasing other specialty slots within the 1996 cap on positions.)
- Due to significant training out of the hospital, most family medicine residency respondents did not have their full residency positions captured in the 1996 cost reports upon which the reimbursement is based, causing a loss of Medicare revenue compared to most other specialties that train almost exclusively in the hospital.

Following are the Academy's four recommendations for solving these problems. These provisions are included in H.R. 1222.

Supporting Residency Training in Ambulatory Sites

H.R. 1222 would treat all hospitals sponsoring residency programs *fairly*—not just those that were training residents in the hospital in 1996—by including those residents who were training in the community in the cap. As you know, the BBA capped the number of residency slots in an institution, a number that determines the amount of indirect graduate medical education funding (IME) the institution receives. Without “resetting” the caps, the residency programs that were training residents in the community in 1996 will have their Medicare IME cap lowered and receive less funding in subsequent years. Ironically, while one intent of the Act was to encourage ambulatory training by providing IME support after 1998, the Act inadvertently did not account for those residents who were *already* training outside of the institution at the time, such as family medicine residents. The Academy supports Medicare funding for all residents training outside of the hospital.

Providing Limited Growth to Single Residency Program Hospitals

H.R. 1222 would allow hospitals that sponsor only one residency program to increase their resident count by one per year, up to a maximum of three, to meet com-

munity needs for primary care physicians. Under the BBA, a hospital with several residency programs can move positions from less popular subspecialty programs to high-demand primary care programs, such as family medicine, to meet the residency caps. By contrast, a hospital with only one program does not have this option. Approximately 300 hospitals sponsor only one residency program; 191 are in family medicine.

Supporting Residency Programs Under Development

H.R. 1222 bill would allow a few, new, family medicine residency programs that have long been under development to be established by extending the cut-off date for new residencies. Specifically, any residency programs that were approved after January 1, 1995, and before September 30, 1999, could be set up. The BBA set August 5, 1997, as the cut-off date for new residencies, which had a disproportionate, negative effect on family medicine residency programs because of the growth in these training programs.

Meeting the Needs of Rural Communities

H.R. 1222 would permit the establishment of new, rural training programs by allowing urban residency programs sponsoring these programs to receive an exception to the caps (for the rural programs only.) The BBA capped all residency programs, but strongly supported the establishment of rural programs. This provision clarifies the intent of the Act by supporting the growth of rural programs.

CONCLUSION

The American Academy of Family Physicians appreciates the opportunity to inform your deliberations on the impact of the BBA on graduate medical education system. Thank you for the opportunity to provide these comments.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

The American Heart Association urges the House Commerce Committee's Subcommittee on Health and Environment to carefully consider the impact of the \$1500 Medicare outpatient rehabilitation services cap on patients' ability to receive the services needed after a heart attack or stroke. The Association appreciates the Subcommittee's efforts to review the impact of the 1997 Balanced Budget Act on patient care and implores the Subcommittee to review the BBA provision establishing the cap and the negative impact it has had on patient care.

Cardiac rehabilitation and stroke rehabilitation are fundamental to the recovery of many heart disease and stroke patients. Yet, the arbitrary \$1500 Medicare cap on outpatient rehabilitation services hinders patients' ability to receive comprehensive care post-incident. In addition, the cap raises severe concerns for patients who suffer multiple cardiovascular events in a single year.

Often cardiovascular events—stroke in particular—require extensive rehabilitative care including speech, physical and occupational therapy. This care can dramatically improve patients' ability to recover from a heart attack or stroke and can improve patients' chances of avoiding a future incident. As a result, access to proper and appropriate rehabilitative care after a heart attack or stroke is not only sound medical policy, it is also sound fiscal policy.

The 4.2 million patients, families, caregivers, healthcare professionals and concerned citizens of the American Heart Association ask the Subcommittee to lift the arbitrary cap established by the BBA and give heart disease and stroke patients access to the care and benefits necessary for their recovery.

Thank you for your consideration of our views. We appreciate the opportunity to share our concerns and look forward to working with the Subcommittee to remedy the situation that has arisen as a result of the rehabilitation cap.

DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

November 16, 1999

The Honorable MICHAEL BILIRAKIS, *Chairman*
House Commerce Committee
Subcommittee on Health and Environment
2125 Rayburn House Office Building
Washington, DC 20515

DEAR CHAIRMAN BILIRAKIS: Thank you for the opportunity to testify before the House Commerce Committee, Subcommittee on Health and Environment on Sep-

tember 15, 1999, regarding the Balanced Budget Act of 1997 and the impact on cost savings and patient care.

Attached is a copy of the edited transcript, along with answers for the record, and responses to additional questions submitted after the hearing.

If you need any additional information, please do not hesitate to contact me. It is essential that we work together for meaningful reform. Your continued interest and support are crucial to the success of the Medicare program and I look forward to continuing to work with you as we address all of these concerns.

Sincerely,

MICHAEL M. HASH
Deputy Administrator

Attachments

cc: The Honorable Thomas J. Bliley, Jr., *Committee Chairman*
The Honorable Sherrod Brown, *Subcommittee Ranking Member*
The Honorable Ted Strickland

QUESTIONS FOR THE RECORD SUBMITTED BY CHAIRMAN BILEY

Question 1. In their testimony, MedPAC says that "there is no systematic evidence to date that beneficiaries' access to care has been impaired" by the BBA? Can you comment on that statement and discuss the access issues across various sites of services, including hospitals, home health agencies, skilled nursing facilities, physical and speech therapists, etc.?

Answer 1. Thus far, our monitoring reveals evidence of isolated but significant problems. Although our analysis is not yet complete, we are concerned that some beneficiaries are not getting necessary care. For example, the BBA imposed \$1500 caps on the amount of outpatient rehabilitation therapy services that can be reimbursed, except in hospital outpatient clinics. However, these caps are not based on severity of illness or care needs, and they appear to be insufficient to cover necessary care for many beneficiaries. We have several industry-sponsored analyses from different sources of 1996 claims data indicating that approximately 12 to 13 percent of therapy patients will exceed the caps. Beneficiary groups are reporting many instances of problems with this cap, and we are very concerned about their adverse impact, particularly on individuals in nursing homes. As mentioned above, our IG colleagues have agreed to study this problem. We are providing data to the Medicare Payment Advisory Commission so it can analyze patterns of therapy service usage. And we will continue to work with Congress and others to determine what adjustments to the cap should be made.

We are also concerned that the new prospective payment system for skilled nursing facilities does not adequately reflect the costs of non-therapy ancillaries such as drugs for high acuity patients. The HHS Inspector General (IG) found, in interviews with hospital discharge planners and nursing home administrators, that less than 1 percent of nursing home administrators say the prospective payment system is causing access to care problems. The proportion of beneficiaries discharged to skilled nursing facilities is unchanged from 1998, and hospital lengths of stay have not increased. However, about one in five discharge planners say it takes more time to place Medicare patients in nursing homes. The IG also found that both nursing home administrators and hospital discharge planners say nursing facilities are requesting more information before accepting patients. About half of the nursing home administrators say they are less likely to accept patients requiring expensive supplies or services such as ventilators or expensive medications. About half also say they are more likely to admit patients who require special rehabilitation services such as physical therapy following joint replacement surgery. We are therefore conducting research that will serve as the basis for refinements to the resource utilization groups that we expect to implement next year. We expect to have the research completed by the end of the year and to then develop refinements that we will be able to implement next October. We believe these changes should be budget neutral. However, we are continuing to review whether we have additional administrative authority. We fully expect that we will need to periodically evaluate the system to ensure that it appropriately reflects changes in both care practice and the Medicare population.

For home health care, evaluations by the GAO and HHS to date have not found that BBA changes are causing significant quality or access problems. However, we have heard reports from beneficiary groups, our regional offices, and others regarding home health agencies that have inappropriately denied or curtailed care, and incorrectly told beneficiaries that they are not eligible for services. We are also hearing reports from beneficiary advocates and others that some high cost patients are having trouble finding home health agencies to provide the care they need. This

may result from a misunderstanding of the new incentives to provide care efficiently, or from efforts to "cherry pick" low cost patients and game the system. The CBO attributes some of the lower health spending to the fact that agencies are incorrectly treating the new aggregate per beneficiary limit as though it applies to each individual patient. We have therefore provided home health agencies with guidance on the new incentives and their obligation to serve all beneficiaries equitably. We have instructed our claims processing contractors to work with agencies to further help them understand how the limits work. And, because home health beneficiaries are among the most vulnerable, we are continuing ongoing detailed monitoring of beneficiary access and agency closures.

For hospitals, the hospital industry has submitted data projecting significant decreases in total Medicare margins. Our actuaries believe the methodology used to develop these projections understates base year total margins by approximately 7 percent. And, as the Medicare Payment Advisory Commission (MedPAC) has noted, Medicare costs per case have declined for an unprecedented fifth year in a row. Hospitals may be having financial difficulties because Medicare payments no longer include enough excess to make up for below-cost contracts with managed care companies or because of other market issues not directly related to Medicare payment. We do, however, share MedPAC's concern that many small rural hospitals appear to be in especially poor financial condition. We have taken administrative steps that will help many rural hospitals, and are continuing to monitor this situation closely, as well.

Question 2. The President, in his Medicare reform plan released in June, said that he is considering delaying the outpatient volume cap for several years. Can you indicate whether HCFA will delay the volume cap?

Answer 2. To help all hospitals with the transition to outpatient prospective payment, we intend to delay a "volume control mechanism" for the first few years of the new payment system. The law requires Medicare to develop such a mechanism because prospective payment includes incentives that can lead to unnecessary increases in the volume of covered services. The proposed prospective payment rule presented a variety of options for controlling volume and solicited comments on these options. Delaying their implementation would provide an adjustment period for providers as they become accustomed to the new system. We also are considering implementing a threeyear transition to this new PPS by making budgetneutral adjustments to increase payments to hospitals that would otherwise receive large payment reductions such as lowvolume rural and urban hospitals, teaching hospitals, and cancer hospitals. Without these budgetneutral adjustments, these hospitals could experience large reductions in payment under the outpatient prospective payment system. And, to help hospitals under the outpatient prospective payment system, we included a provision in the proposed rule to use the same wage index for calculating rates that is used to calculate inpatient prospective payment rates. This index would take into account the effect of hospital reclassifications and redesignations. We sent a letter to you on October 19, discussing our plans for the final rule in more detail.

Question 3. In GAO's testimony, they indicate that the hospital industry overstates the impact of the BBA on hospital margins. Can you comment on that statement?

Answer 3. Industry projections show significant deterioration in hospital margins. However, our actuaries believe the methodology used to develop these projections was flawed and understates base year total margins by approximately 7 percent in the base year. When adjusted for this error, alternative 2002 projections of total Medicare margins would range from 2.3 to 9.3 percent. It is important to note that the most recent MedPAC data show that hospitals' Medicare costs per case have declined for an unprecedented fifth year in a row, and that hospitals' average Medicare inpatient margin was a record 17.1 percent in 1997. So despite slower revenue growth, hospitals' aggregate total margins have increased steadily. We are, however, concerned about MedPAC data suggesting that many small rural hospitals appear to be in especially poor financial condition, and about the combined impact of all the various BBA payment changes on rural hospitals. The President's Medicare reform plan includes changes to regulations that would lessen the impact on these facilities.

Question 4. The Medicare Payment Advisory Commission, the American Hospital Association, and the American Medical Association do not support the use of the ambulatory patient classification systems (APCs) and instead support payment on a service specific fee schedule. Would you support movement to a payment system that reimburses hospitals on a specific procedure basis?

Answer 4. Our proposed prospective payment system for hospital outpatient departments (OPDs) does, in fact, define the unit of payment based on the individual

service the hospital furnishes. It includes things furnished as an integral part of the procedure or visit such as supplies, anesthesia, drugs, blood, recovery room, etc. We do not propose to package payment for things that are related, but are not an integral part of the service, such as ancillary laboratory, or other diagnostic tests.

Grouping services is separate from defining a unit of service. Although the payment is based on the individual unit of service, it is calculated by grouping services that are similar clinically, and with respect to resource use. The median cost for each service in a group is calculated and then the median cost of all services within the group is determined. This group median cost is then used to calculate a relative weight that applies to the individual services in the group. Although we group services to calculate a group payment amount, our proposed system also may be viewed as a fee schedule that applies the same payment to similar services.

We received a number of comments and recommendations as a result of the comment period of the proposed rule and are in the process of analyzing them. We will respond to these recommendations in the final rule.

Question 5. As we know, there are winners and losers with the implementation of every new payment system. We have heard a lot from providers who have complained about the APC system, but not from the ones that will benefit. Can you identify the groups who have benefited to us and explain why their reimbursement rates went up?

Answer 5. Those providers with more positive impacts are hospitals that have lower than average costs, or who used more accurate procedure coding under the current system. However, these projections in the proposed rule are based on current medical and billing practices, which will likely change after the system is implemented. Past experience tells us that these changes tend to produce much better financial impacts on hospitals than were projected. Attached is a chart identifying the groups who have benefited.

Question 6. There were considerable problems in implementing the SNF PPS and outpatient therapy fee schedule, resulting in delayed payment and providers having to reprocess bills for coinsurance changes. Given that HCFA will need to implement major software changes for SNF and home health payment systems, how do you propose to handle another major computer change in July 2000 when you implement the outpatient PPS? What are you doing to ensure that millions of beneficiaries do not end up paying higher coinsurance and that hospitals don't have to reprocess millions of bills if the system is only partially or incompletely installed by July 1?

Answer 6. We implemented SNF PPS in July 1998 without major problems. There were implementation issues with SNF consolidated billing for Part B services; however, because we delayed implementation of this provision due to our Y2K systems priorities, these problems were put in abeyance. Since implementation of SNF PPS, we have gained valuable experience with implementing systems changes. We now have an Agencywide change management program that is designed to assure that instructions to Medicare contractors are thoroughly coordinated within HCFA and, because of rigid time frames, final instructions are communicated to contractors well in advance of implementation. We are more fully including our contractors and standard system maintainers in planning activities for implementing systems changes. In addition, our experience in managing contractor Y2K compliance has reinforced the importance of thorough testing of systems changes. That experience is being translated into additional testing of systems changes through the use of outside Beta testing contractors. We believe the lessons we have learned have been invaluable and will enable us to more smoothly implement systems changes like PPS in the future.

Question 7. In developing the APC system, you utilized 1996 cost data. Given the speed at which new drug therapies are entering the marketplace, (many after 1996) how do you propose developing reasonable reimbursement rates for these new products? How long will it take you to develop payment rates for new products? Do you think that all drug therapies can be effectively captured within the APCs? Is it appropriate to include orphan drugs within an APC system?

Answer 7. As will be specified by the final rule, we have responded to comments on these very important issues. Where drugs are not considered appropriate to package with another procedure in an APC, options for assigning separate APCs for that drug or drugs are being developed. The final rule will specify how new technologies will be priced for the system on a rapid turn around basis. All technologies that could not have been recognized in the 1996 data will be considered as new technologies for this policy. Prices for new technologies can be implemented with the quarterly updates to HCFA's contractor systems. We have further outlined our plans for the final rule in our October 19 letter to you.

Question 8. HCFA has stated that the therapy cap will be implemented on a per-provider basis due to your inability to track a beneficiary's use of services. Will you be able (and do you intend) to implement it as a per-beneficiary cap after Y2K?

Answer 8. After Y2K, we intend to implement the therapy caps on a per beneficiary basis. However, we are concerned that the caps are adversely affecting beneficiaries' access to needed services. We want to work with Congress on legislation to make changes to the cap.

Question 9. What is your opinion about the need for changing the reimbursement levels for home health agencies? Do you agree with GAO's analysis that access to home health services has not been harmed by the BBA?

Answer 9. Our monitoring of the impact of BBA shows that overall there does not appear to be an access problem to home health services. We are concerned with access and will continue to monitor this closely. We will also continue to keep you posted on our monitoring and look forward to working with you on BBA refinement legislation to ensure access to care.

Question 10. What are the pitfalls associated with raising the therapy cap from its current \$1500 limit? Would it be wiser to move to one overall cap, say \$3000, or have three separate caps, one each for PT, and ST, and OT?

Answer 10. We continue to be concerned about these caps, and are troubled by anecdotal reports about the adverse impact of these limits. The HHS Inspector General (IG) has agreed to study the impact of the caps. The IG's initial analysis of 1998 data on SNF therapy services, under Medicare Part B, indicates that 29% of beneficiaries receiving services would have exceeded a joint physical/speech therapy cap of \$1500; 26% would have exceeded a physical therapy-only cap of \$1500; and, 22% would have exceeded a speech-only cap of \$1500. Further study by the IG and others will help us determine whether, and how, any adjustments should be made. We will continue working with beneficiaries, providers, Congress, and other interested parties to closely monitor the situation, evaluate evidence of problems in access to quality care, and develop appropriate, fiscally responsible solutions. As follow-up to our round table discussion, I've provided the Committee with an analysis of various options for changing the caps.

Question 11. Has HCFA determined or estimated the total number of SNF beneficiaries who will meet the caps this year or in any year? Do you know how many of these instances are secondary episodes of illness or accidents in one year?

Answer 11. As mentioned above, the IG's initial analysis of 1998 data on SNF therapy services, under Medicare Part B, indicates that 29% of beneficiaries receiving services would have exceeded a joint physical/speech therapy cap of \$1500; 26% would have exceeded a physical therapy-only cap of \$1500; and, 22% would have exceeded a speech-only cap of \$1500. Further study by the IG and others will help us determine whether, and how, any adjustments should be made. However, at this time, we do not know how many instances are secondary episodes of illness or accidents in one year. Such a determination would require extensive data analysis and could not be completed in a short period of time.

Question 12. What would it take for HCFA to speed up the creation of a less arbitrary, diagnosis-related coverage system? What is the earliest it could be implemented?

Answer 12. We support establishing a payment system for outpatient therapy services tied to patient needs rather than defined by an arbitrary, uniform dollar limitation. However, our investigations and research thus far to determine the impact of the therapy caps required by the Balanced Budget Act of 1997 on patient access to outpatient rehabilitation services, have already revealed that patient diagnosis extracted from claims data may not be adequate to predict utilization. At a minimum, patient diagnosis is going to have to be supplemented by variables such as functional status and patient capacity for improvement.

Unfortunately, calibrating a payment system that is attuned to, and responsive to, the outpatient therapy needs of Medicare beneficiaries, requires information that simply is not available at this time either within or outside of HCFA. There are no short cuts to setting up a good, comprehensive, flexible payment system. We have to collect a critical mass of data that accurately classify patient needs using stilltoberecreated tools such as functional assessment measures; process these data; and, then design a payment methodology in a budget neutral manner. This process could take many years and would be resource intensive.

In the meantime, the most expedient shortterm alternative to the longer-range development of a comprehensive payment system seems to lie with legislative changes to either raise or reconfigure the caps in some way.

Question 13. Does HCFA have any data on the most common diagnosis groups that meet or exceed the caps? In your opinion, what Part B services are appropriate to exclude from a consolidated billing requirement?

Answer 13. We are very concerned about the anecdotal reports regarding the adverse impacts of these caps. Data using specific procedure codes are just now becoming available. We will examine therapy claims data to determine which beneficiaries exceed the caps. However, we do not think that diagnosis accounts very well for levels of therapy utilization. Data on functional status may be very useful in this regard, but it is not currently collected.

With respect to excluding services from consolidated billing requirements, using our limited discretion as afforded by the statute, we have administratively excluded certain types of exceptionally intensive outpatient hospital services that lie well beyond the scope of the care SNFs would traditionally furnish. Examples of these types of services include outpatient surgery, MRIs, radiation therapy, and emergency services. We are currently considering excluding additional outpatient hospital services such as certain chemotherapy services. Establishing exclusions in settings other than outpatient hospitals would require a change in statute.

Question 14. What types of administrative changes are you considering to SNF PPS?

Answer 14. We are carefully reviewing the possibility of making budget neutral administrative changes to the prospective payment system for skilled nursing facilities (SNF PPS).

The BBA mandated a per diem SNF PPS covering all routine, ancillary, and capital costs related to covered services provided to beneficiaries under Medicare Part A. The law requires the use of 1995 costs as the base year, and implementation by July 1, 1998, with a three-year transition blending facility-specific costs and prospective rates. It did not allow for exceptions to the transition, carving out of any service, or creation of an outlier policy.

This past Spring, we held a town hall meeting to hear a broad range of skilled nursing facility concerns, and we continue to meet with provider and beneficiary representatives. We recognize there are concerns that the SNF PPS does not adequately reflect the costs of non-therapy ancillaries such as drugs for high acuity patients.

As mentioned previously, the HHS Inspector General survey does not suggest that the SNF PPS prospective payment system is causing access to care problems at this time. And the proportion of beneficiaries discharged to skilled nursing facilities is unchanged from 1998, and hospital lengths of stay have not increased. However, there is some indication from the survey that it does take more time to place Medicare patients in nursing homes, and facilities are requesting more information before accepting patients. About half of the nursing home administrators responding to the survey indicated they are less likely to accept patients requiring expensive supplies or services. About half say they are more likely to admit patients who require special rehabilitation services such as physical therapy following joint replacement surgery.

We are conducting research that will serve as the basis for refinements to the resource utilization groups (RUGs) that we expect to implement next year. We expect the research to be completed by the end of 1999 and to then develop refinements for implementation in October 2000. We believe these changes should be budget neutral. However, we are continuing to review whether we have additional administrative authority. We fully expect that we will need to periodically evaluate the system to ensure that it appropriately reflects changes in care practice and the Medicare population.

Question 15. Do you believe that non-therapy ancillary services were under-accounted for in the final SNF PPS?

Answer 15. Again, the HHS Inspector General survey indicates that about one in five discharge planners say it takes more time to place Medicare patients in nursing homes. And about half of the nursing home administrators indicated they are less likely to accept patients requiring expensive supplies or services, which may suggest that some refinements to the resource utilization groups (RUGs) are necessary.

As mentioned above, we are currently conducting research in this area and our findings will serve as the basis for refinements that we expect to implement in October 2000. Again, we expect that we will need to evaluate the RUG periodically to ensure that it appropriately reflects changes in care practice and the Medicare population.

Question 16. Do you believe that, due to increases in the acuity levels since 1985, many facilities will be severely disadvantaged by the transition period?

Answer 16. We are concerned about paying SNFs appropriately for the care of patients. We do not believe that many facilities will be severely disadvantaged by the transition period due to increases in the acuity levels since 1995. First and foremost, under the PPS, SNFs have the ability to provide care more efficiently than in the past. It has been suggested by the OIG and GAO in several reports that the rates

may be somewhat inflated as a result of being based on data from the prior cost reimbursement system where incentives often directed providers to operate inefficiently. Secondly, the three-year transition period blends facility-specific and Federal prospective rates. The Federal rates are casemix adjusted according to clinical and functional characteristics of SNF residents and will allow higher payments for higher acuity. We are currently doing research to refine the RUGs, which will make them even more sensitive to a patient's care needs. There are legislative proposals that allow SNFs to bypass the transition.

Question 17. What other options has HCFA considered to deal with SNF residents with very high drug costs, ventilators, or other expensive care not taken into account by the PPS?

Answer 17. The SNF PPS, through casemix classification and adjustment, currently reflect a full range of SNF patient types with varying characteristics and degrees of resource intensity. Through research and refinement to the PPS, we will try to ensure that the PPS not only continues to account for a high level of resource intensity, but improves in terms of its sensitivity to non-therapy ancillaries, highly complex cases and less common conditions or patient types. We engaged in research to determine the potential for making refinements to the current casemix model to improve accuracy of the payments. We note that the law does not give us the direction to adopt some of the options contained in the comments to the SNF PPS regulations such as creation of an outlier policy or cost-based payments for nontherapy ancillary services.

Question 18. Do you have any figures on losses for different RUGs categories?

Answer 18. Currently we have little data in this area. However, we have recently commissioned a research contractor to develop data and analysis as part of our overall effort to make refinements to the PPS. We plan to have this research completed and refine the system next year. We note that the OIG's recent report on access in SNFs noted that discharge planners were finding it easier to place rehabilitation patients in SNFs due to the relatively higher reimbursement rates for special rehabilitation. The majority of Medicare SNF patients fall within the rehabilitation RUGs.

Question 19. Do you believe the new PPS has had an impact on the current spate of bankruptcies in the SNF community?

Answer 19. We are concerned about the impact of the PPS on the industry. However, in our initial analysis, we have not found it to be a major contributor to the bankruptcy filings. According to a July 1, 1999 Business Week article, financial analysts have been quoted as saying that the financial instability of the SNF community is primarily due to over leveraging when Congress cutback on Medicare and for high-priced acquisitions at the wrong time.

We are continuing to monitor the impact of PPS on various provider groups and will continue to keep you informed on our analysis.

Question 20. Do you any idea how many residents are at risk due to closures of SNFs?

Answer 20. We do not expect to be faced with the widespread closure of SNFs due to changes imposed by the BBA. Recently, we have seen activity by several large nursing homes of filing for bankruptcy. This filing is for Chapter 11 only, which primarily reorganizes the company's organization structure and does not affect patient care. We are working with States to closely monitor the quality of care in nursing homes belonging to a Chapter 11 chain. We also routinely work with the States in the event of a SNF closing ensuring the health and safety of the resident is not compromised.

Question 21. In the July 1999 update for home health cost limits, HCFA reported that over 90 percent of all home health agencies will be over either the per-beneficiary or per-visit limits. Is this accurate? Please provide the appropriate back up data to support your answer.

Answer 21. The August 5, 1999 Federal Register notice, indicating the per-beneficiary and per-visit limits under the IPS for FY2000, estimates that 15 percent of HHAs will be subject to the per-visit limitation while 79 percent will be subject to the per-beneficiary limitation. The remaining agencies will receive their actual costs. No one agency will be limited by more than one limit.

The FY 2000 limits are applicable to cost reporting periods, or portions of cost reporting periods, beginning on or after October 1, 1999. While the PPS is scheduled to be implemented on October 1, 2000, the estimates made in the August 5th regulation assume the continuation of IPS minus the statutory 15 percent cut in payment limits mandated for October 1, 2000, if the PPS does not go into effect. As such, for those agencies whose cost reporting periods end after October 1, 2000, the estimate reflects the 15 percent cut in payment limits that would take effect. We plan to implement the home health PPS on October 1, 2000, and we published the notice of proposed rulemaking on October 28, 1999.

The Balanced Budget Act of 1997 required that the IPS be based on data from 12-month cost reporting periods ending during FY 1994 and updated to the current years. The attached table shows the estimated impact of the IPS on HHAs, effective October 1, 1999. Column one of this table divides HHAs by number of characteristics including their ownership, whether they are old or new agencies, whether they are located in an urban or rural area, and the region in which they are located. Column two shows the number of agencies that fall within each characteristic or group of characteristics. Column three shows the percent of HHAs within a group that are projected to exceed the per-visit limitation (and therefore will not be affected by the per-beneficiary limitation) before the behavioral offsets are taken into account. Column four shows the average percent of costs over the per-visit limitation for an agency in that cell, including behavioral offsets. Column five shows the percent of HHAs within a group that are projected to exceed the per-beneficiary limitation (and therefore will not be affected by the per-visit limitation) before the behavioral offsets are taken into account. Column six shows the average percent of costs over the per-beneficiary limitation for an agency in that category, including behavioral offsets. It is important to note that in determining the expected percentage of an agency's costs exceeding the cost limitations, column four (percent of costs exceeding visit limits) and column six (percent of costs exceeding beneficiary limits) cannot to be added together. Either the per-visit limitation or the per-beneficiary limitation is exceeded, but not both.

Question 22. Can you assure us that the PPS for home health services will be ready to be implemented by October 1, 2000?

Answer 22. Yes, we published the proposed rule for the home health prospective payment system on October 28, 1999, and we expect to have the system in place by the October 1, 2000 statutory deadline.

Question 23. How are home health agencies coping with new regulatory changes such as OASIS, new billing requirements and the 15-minute visit increment reporting?

Answer 23. There have been a number of challenges that home health agencies have faced since the enactment of the BBA and we have worked to use administrative flexibility where possible under the law. This past July 19, agencies began collecting OASIS data. On August 24, 1999 agencies began transmitting OASIS data to states. We have provided free software called HAVEN (Home Assessment Validation and Entry) that can be used for encoding and transmission. While we are just beginning the second month of receiving data, the early agency response is favorable. Currently, we have over 2 million records of completed OASIS assessments in the national repository.

Early evidence suggests that providers are managing well with OASIS. Assessments, such as the OASIS are not a new requirement. It is important to realize the HHAs have been and will continue to do comprehensive assessments of their clients. Doctors, nurses, and therapists are trained to do such assessments as part of their routine care. Such assessments are critical for providers to know if patients' needs are being met or they are improving. OASIS merely *standardizes* such assessments. A motion study was performed by our contractor analyzing the initial assessment (time spent with patient and time spent on documentation). On average, by standardizing the assessment, total time spent is the same, but time spent on documentation decreased. This allows more time to be spent with the patient. Such standardization allows for efficiency in addition to accurate payment and quality oversight and improvement.

Regarding the 15-minute increment, the BBA required that home health agencies report the number of 15-minute increments comprising each service, otherwise, "...no claim for such services may be paid..." The purpose of this provision is to obtain data that might be useful in developing or refining a home health prospective payment system (PPS). It will not affect the amount of payments to home health agencies under the IPS or the PPS. We have met with industry representative to clarify how the 15-minute reporting requirement should be implemented and have made this information available on our website. In order to allow agencies significant time to implement this requirement, we phased it in over a three-month period from July 1 to October 1, 1999. However, we continue to hear complaints from agencies about this requirement that range from the burden of recording and reporting this information to what activities should or should not be included in the reporting.

Question 24. What type of guidance have you provided the industry and your own claims processors to ensure care is not inappropriately denied? Has any agency been sanctioned for denying access to care as a result of their misunderstanding of the new law?

Answer 24. HHAs have been receiving guidance on the appropriate manner in which the per-visit and per-beneficiary limits under the IPS must be applied. When

it became clear, shortly after the IPS began that some agencies may erroneously be applying the limits to individual beneficiaries, rather than applying the limits in the aggregate, the Administrator send a letter to all HHAs clarifying the issue. In her February 3, 1998 letter, the Administrator wrote, "The new aggregate cap reflects the typical utilization of home health services for each HHA during the FY 1994 base period established by Congress. It allows HHAs to balance the cost of caring for any one patient against the cost of caring for all patients. We believe all Medicare enrollees can be safely and efficiently cared for under this payment system by HHAs that deliver quality care efficiently . . . Any reports of HHAs misinforming beneficiaries or inappropriately terminating care for Medicare enrollees will be considered the basis for a complaint survey that could lead to termination of the HHA from Medicare."

We continue to address the issue with our regional offices, who along with the states, are investigating complaints that we receive concerning inappropriate discharges or cutting back on covered services. Agencies found to have substantiated complaints made against them are required to submit an acceptable plan of correction to us or our agents. We and the state agency will resurvey the agency some time after the plan of correction is submitted to ensure that the agency has come into compliance. If the agency has not, it can be terminated.

The five Medicare claims processors for home health have continually been performing provider education for HHA associations and individual agencies on the IPS, based upon HCFA program memorandum and notices describing how the IPS should be implemented.

Question 25. Do you agree with GAO's analysis that access to home health services has not been harmed by the BBA?

Answer 25. Home health beneficiaries are among the most vulnerable and we are closely monitoring the effects of the BBA changes on beneficiary access to home health care and agency closures. To date, evaluations by the GAO and HHS have not found that the changes are causing significant quality or access problems in the home health area.

Our monitoring of employment data indicates that freestanding home health agencies have made small reductions in their workforce, back to the level seen in 1996. We have heard reports from beneficiary groups, our regional offices, and others regarding home health agencies that have inappropriately denied or curtailed care, and incorrectly told beneficiaries that they are not eligible for services. We are also hearing reports from beneficiary advocates and others that some high cost patients are having trouble finding home health agencies to provide the care they need. This may result from a misunderstanding of the new incentives to provide care efficiently, or from efforts to "cherry pick" low-cost patients and game the system.

In order to address this, we have provided home health agencies with guidance on the new incentives and their obligation to serve all beneficiaries equitably. We have instructed our claims processing contractors to work with agencies to further help agencies understand how the limits work. I assure you we will continue to monitor the situation closely.

Question 26. How would you respond to agencies who claim that your own regulation of August 5 regarding cost limits predicts that 93.5% of surviving agencies will exceed their FY 2000 per-beneficiary cost limit or per-visit cost limit and that on average, agencies will have to repay HCFA 12% of its Medicare costs?

Answer 26. The law requires that HHAs receive the lower of their actual costs or their actual costs up to the per visit limit or their actual costs up to the per beneficiary limit. The August 5, 1999 Federal Register notice, which informs agencies about the per-beneficiary and per-visit limits under the IPS for FY2000, estimates that 15 percent of HHAs will be limited by the per-visit limitation while 79 percent will be limited to the per-beneficiary limitation. The remaining agencies will be limited to their actual costs. For those agencies limited by the per-beneficiary limits, the average percent of the agency's costs exceeding the per-beneficiary limitation is 12.1 percent. Those agencies limited by the pervisit limit will on average have 1.3 percent of their costs exceed the pervisit limit. Because the interim rates have been calculated to reflect the level of the limits, the amount of actual costs exceeding the applicable limit for any one agency will not be paid to the agency by Medicare. Medicare will pay only up to the applicable cap, not in excess of it.

Because agencies have now had two years of experience under the IPS they are better able to perform efficiently. The data upon which the estimate of the percent of agency costs exceeding either limit predates the IPS. Therefore the estimates likely inflate the average percent of costs that agencies will incur above the limits.

Question 27. Please respond to the following from the testimony of the American Medical Association. "In the first two years of the SGR, erroneous HCFA estimates

have already shortchanged physician payments by more than \$3 billion. These projection errors have not been corrected and HCFA does not plan to do so. Specifically, one year after the 1997 notice, HCFA reneged on its pledge to correct SGR errors and simultaneously issued its most egregious error projecting Medicare managed care enrollment would rise 29 percent in 1999, despite the many HMOs abandoning Medicare in 1999."

Answer 27. After BBA was enacted, our actuaries identified problems with the SGR target. Specifically, they found that once the SGR target is set for a year, it cannot be changed, even to correct for estimation errors and even if better data on elements in the SGR formula are subsequently available compared to when the SGR was set. This problem was discussed in the November 2, 1998 *Federal Register* notices on the FY 1999 SGR. While we had initially thought that this latter problem could be dealt with under current law, the HHS General Counsel has indicated current law will not permit us to fix the problem. In our September 30, 1999, *Federal Register* notice, we confirmed that we could not make adjustments for projection errors under existing authorities.

The President's FY 2000 budget contains a legislative proposal for a budget-neutral technical fix to solve this problem. The proposal would correct projection errors automatically beginning with the CY 2000 SGR. The proposal would also make adjustments for the two historical years of SGR (FY 1996 and FY 1999). However, this aspect of the provision would result in a cost to the program. Technical changes to the SGR system would offset some of the costs of correcting for projection errors. We have also proposed an adjustment to make the proposal budget neutral. If our legislative proposal only corrected for projection errors and did not also include other changes to make it budget neutral, it would provide physicians with additional payments relative to current law.

Correcting for projection errors could work to either increase or decrease the physician fee schedule update. Under the SGR system to date, correcting for projection errors would have the effect of increasing the physician fee schedule update. However, under the prior Medicare Volume Performance Standard (MVPS) system, we also did not correct for projection errors. Those projection errors tended to overstate the MVPS and the subsequent updates. We would like to continue to work with the Congress and the AMA on a legislative solution that provides more stability to the system and requires the Secretary to correct estimation errors.

Question 28. What authority do you believe you have to correct for inaccurate assumptions on the SGR, particularly in light of the cumulative effect of these calculations?

Answer 28. According to the General Counsel's office, the language of the statute is clear: we do not believe that we have the authority to make adjustments. In our October 1, 1999, *Federal Register* final notice, we confirmed that we could not make adjustments for projection errors under existing authorities.

Question 29. As we understand it, the American Medical Association and the specialty groups first wrote the HCFA Administrator about their concerns with the projection errors in the Sustainable Growth Rate on December 2, 1998 (within the comment period on HCFA's November 2, 1998 SGR Notice). Then they sent another letter to HCFA about this problem on May 21, 1999. Has the HCFA Administrator responded to these letters from the physician community?

Answer 29. Because of the volume of written comments on proposed rules, notices and regulations, we do not generally respond in writing to comments on proposed rules. We do try to address comments on any proposal notice or rule in the corresponding final versions, as appropriate. The December 2, 1998 letter was a comment on a final rule with comment period published in the *Federal Register* on November 2, 1998. We specifically addressed the December 2, 1998 comment in the final notice published in the October 1, 1999 *Federal Register* (Vol. 64, No. 190, page 53396).

The March 21, 1999 letter addressed issues raised in the November 2, 1998, final rule, but was not a public comment. We responded directly to the signers of that letter on September 24, 1999. A copy of our response is attached.

Question 30. Can you tell us the status of your proposed rulemaking to change your policy on coverage of self-administered injectable drugs in a physician's office? Please provide us with the statutory and the policy rationale for this proposed change.

Answer 30. By law, Medicare covers only those drugs approved by the Food and Drug Administration that are furnished incident to a physician's services and cannot be self-administered. There are a few exceptions that are explicitly provided in section 1861(s)(2) of the Social Security Act. Historically, we have interpreted this coverage restriction as it pertains to the characteristics of the drug, not to the capacity of a beneficiary's ability to self-administer any drug. Nevertheless, because

of concerns expressed by Congress and others regarding the specific capacity of individual beneficiaries to self-administer, and the recognition of the evolving state of medical practice, we have decided to review our current position. To appropriately elicit input and comment for relevant stakeholders on this issue, we intend to develop a proposed rule to better define the term "self-administered." The development of a number of options for defining "self-administered" and the issuance of the proposed rule will be a high priority.

Question 31. HCFA's final rule implementing BBA 97 denies payment for telemedicine store and forward applications. In the rule, HCFA said that in order to qualify as a "consultation," all practitioner/provider encounters had to occur in real time. Please provide an explanation for this decision and explain to us whether you believe you have the statutory authority to change this decision.

Answer 31. Medicare payment for teleconsultation, as provided in the November 8, 1998 final rule, represents a significant improvement over traditional Medicare policy for rural areas by allowing payment for a service that historically has required a face-to-face, "hands on" encounter. Under the regulation, a teleconsultation is an interactive patient encounter that must meet criteria for a given consultation service included in the American Medical Association's Current Procedure Terminology. The technology used to deliver a teleconsultation must allow the consultant to conduct an examination in "real time" using interactive audio and video equipment.

This rule represents a first step in refining face-to-face requirements for a medical service under Medicare to accommodate telemedicine services. We are open to developing modifications to Medicare telemedicine coverage and payment policies as the law permits and as more program experience in this area is obtained. The Secretary has identified several issues related to teleconsulting, including the use of store-and-forward technologies for delivering medical services that need to be addressed further. The Secretary has directed us to specifically examine the policy and financial implications of these technologies, as well as the use of registered nurses and other medical professionals not recognized as practitioners under Medicare to present the patient to the consulting practitioner, and the appropriateness of current consultation codes for reporting consultations delivered via communications systems.

Question 32. HCFA has interpreted the BBA97 telemedicine provisions to require the presence of a "presenting practitioner" in order for the encounter to qualify for telemedicine reimbursement. The presenting practitioner must be a health care provider eligible for Medicare reimbursement such as a physician, a nurse practitioner, or a physician assistant. Registered and licensed practical nurses are not permitted to serve as presenters. Please provide us with your rationale in limiting reimbursement to "presenting practitioners." Also, do you believe that this decision will harm access to telemedicine for patients in rural areas? Do you have any plans to revisit this interpretation?

Answer 32. Our decision to require the telepresenter to be a medical professional which is recognized as a practitioner under the Medicare program was determined by the BBA 1997. Section 4206(a) of BBA specifies that the individual physician or practitioner providing the professional consultation does not have to be at the same location as the physician or practitioner furnishing the service to the beneficiary. We believe this language is limiting and requires that a practitioner, as recognized under section—1842(b)(18)(C) of the Act, must be present with the patient during the teleconsultation. Since the same phrase describes the medical professional at both ends of the teleconsultation, we believe that it would be difficult to interpret the phrase to have one meaning for purposes of identifying the consultant and a different meaning for purposes of identifying who may be physically with the patient. Therefore, registered nurses, and other medical professionals not recognized as practitioners under section 1842(b)(18)(C) cannot act as presenters during teleconsultations.

This statutory language could place an additional barrier on Medicare beneficiaries to receiving teleconsultation; especially in areas where there is a shortage of health care practitioners. We have already made plans to revisit this issue and are currently evaluating the use of nurses as telepresenters.

Question 33. HCFA has interpreted the BBA97 provisions to authorize Medicare payments only for those CPT codes which include the word "consultation." Please provide us with your rationale for this interpretation and include commentary about whether it is appropriate to include direct services provided by clinical psychologists, clinical social workers, and physical, occupational, and speech therapists within this definition.

Answer 33. The BBA limits the scope of coverage to professional consultation for which payment is currently made under Medicare. We believe that a consultation is a specific service that meets the criteria specified for a consultation service in the

AMA 1998 Current Procedure Terminology. BBA does not give authority to cover services beyond consultation under this provision.

Under existing Medicare policy, clinical psychologists, clinical social workers, physical, speech and occupational therapists can not bill, nor receive payment, for consultation services under Medicare. Therefore, these practitioners are prohibited from billing a teleconsultation because under Medicare no payment would be made to these practitioners for providing a consultation service.

We recognize that the teleconsultation rule is a first step in defining face-to-face "hands on" requirements for a medical service under Medicare to reflect a telemedicine service. We are not eliminating the possibility of the development of modifications to Medicare telemedicine coverage and payment policies as the law permits and as more program experience in this area is obtained. As previously mentioned, we are currently exploring several issues, including the use of store and forward technologies as a method for delivering medical services and the use of registered nurses and other medical professionals not recognized as a practitioner under the teleconsultation provision to present the patient to the consulting practitioner. Additionally, we are examining the appropriateness of current consultation codes for reporting consultations delivered via communications systems. We plan to provide the Secretary with policy recommendations regarding these issues.

Question 34. On several occasions, we have orally asked for a copy of the contract HCFA signed with 3M when it decided to utilize 3M's services to review the comments and perform consulting work on the final hospital outpatient prospective payment system rule. Please provide us with a copy of this contract and any supporting memorandum which you used to justify your decision to hire 3M.

Answer 34. We apologize for the delay in providing the 3M contract. Attached, to be included as part of the answers for the record, is a copy of the contract and supporting requisition justifying our decision for hiring 3M.

QUESTIONS FOR THE RECORD SUBMITTED BY REP. STRICKLAND

Question 1. Mr. Hash, from your vantage point as the Deputy Director of the Health Care Financing Administration, you have heard complaints from Members of Congress and health care providers about the negative affects of the Balanced Budget Act. In your judgement, are there patients being denied necessary and vital care as a result of the BBA provisions enacted by Congress and carried out by HCFA?

Answer 1. Thus far, our monitoring reveals evidence of isolated but significant problems. Although our analysis is not yet complete, we are concerned, for example, that some beneficiaries are not getting necessary care because of the BBA's \$1500 caps on certain outpatient rehabilitation therapies. We will continue working with beneficiaries, providers, Congress, and other interested parties to closely monitor the situation, evaluate evidence of problems in access to quality care, and develop appropriate, fiscally responsible solutions.

Question 2. Does HCFA believe that the crisis situation created by the Balanced Budget Act is of such a proportion that it warrants immediate action by Congress? And if so, would HCFA please relay to the Committee which BBA provisions it feels Congress should address in order to restore patients' access to quality of care?

Answer 2. We are pleased that both the House and the Senate are considering legislation to address some of the unintended consequences of the Balanced Budget Act. The President is committed to ensuring enactment of such needed legislation this year. In 1997, we worked together to enact important reforms that contributed to extending the life of the Medicare trust fund to 2015. As with any major legislation, the BBA included some policies that are flawed or have unintended consequences. The Administration has taken numerous administrative actions to address these problems and provided funding for legislative fixes in the context of the President's comprehensive Medicare reform plan. We want to work together during the final days of this Congressional session to take action to moderate some of the policies included in the BBA.

ATTACHMENT FOR ANSWER 5

Impact of Outpatient PPS As Proposed

Note: Impact likely to change in final rule

	Percent Change in Medicare Outpatient Payments	Percent Change in Total Medicare Payments
All	-5.7	-0.6
Urban		
All	-5.3	-0.5
0-99 beds	-7.3	-1.1
100-199 beds	-4.2	-0.4
200-299 beds	-3.8	-0.3
300-499 beds	-4.8	-0.4
500+ beds	-9.7	-0.8
New England	-3.2	-0.3
Middle Atlantic	-9.7	-0.8
South Atlantic	-5.8	-0.5
East North Central	-4.3	-0.5
East South Central	-1.8	-0.1
West North Central	-6.5	-0.6
West South Central	-7.4	-0.7
Mountain	-2.2	-0.2
Pacific	-1.8	-0.2
Puerto Rico	8.5	0.6
Rural		
All	-7.4	-1.1
0-49 beds	-13.8	-2.7
50-99 beds	-8.4	-1.3
100-149 beds	-6.0	-0.8
150-199 beds	-4.3	-0.6
200+ beds	-2.9	-0.3
New England	-12.2	-2.1
Middle Atlantic	0.2	0.0
South Atlantic	-7.7	-0.9
East North Central	-6.1	-1.0
East South Central	-6.5	-0.7
West North Central	-10.9	-2.1
West South Central	-10.6	-1.5
Mountain	-8.3	-1.4
Pacific	-3.4	-0.6
Puerto Rico	28.5	1.9
Rural Referral Center	-2.3	-0.3
Sole/Essential Access Community	-12.9	-2.1
Medicare Dependent	-11.3	-2.1
Teaching		
Non-Teaching	-5.1	-0.6
Minor	-4.4	-0.4
Major	-10.6	-1.0
Specialty		
Eye and Ear	10.4	3.2
Trauma	-8.4	-0.8
Cancer	-32.4	-3.1
TEFRA		
Rehab	-21.2	-0.4
Psychiatric	-0.5	-0.3
Long Term Care	-19.6	-0.7
Children	-23.9	-2.2

IMPACT OF TABLE 8.—THE IPS HHA LIMITS, EFFECTIVE 10/1/99

	Number of agencies	Percent of agencies exceeding visit limits	Percent of costs exceeding visit limits	Percent of agencies exceeding beneficiary limits	Percent of costs exceeding beneficiary limits
GEOGRAPHIC AREA					
ALL AGENCIES	7161	14.9	1.3	78.6	12.1
FREESTANDING	4703	6.8	0.3	86.0	14.1
HOSPITAL-BASED	2458	30.4	2.8	64.3	9.1
OLD AGENCIES	4467	17.2	1.8	78.2	10.3
FREESTANDING	2467	7.9	0.4	87.6	11.5
HOSPITAL-BASED	2000	28.6	2.7	66.7	9.1
NEW AGENCIES*	2693	10.9	0.3	79.2	17.2
FREESTANDING	2235	5.5	0.3	84.3	18.4
HOSPITAL-BASED	458	37.2	4.1	64.3	9.4
ALL URBAN	4812	15.2	1.5	79.1	12.0
FREESTANDING	3367	7.1	0.4	85.7	14.0
HOSPITAL-BASED	1215	36.0	3.0	60.4	9.1
OLD AGENCIES	2574	16.0	1.7	82.0	10.2
FREESTANDING	1611	8.9	0.5	88.3	11.4
HOSPITAL-BASED	963	37.6	2.9	62.4	9.1
NEW AGENCIES	2038	12.2	0.9	74.8	16.9
FREESTANDING	1799	5.5	0.3	83.4	18.0
HOSPITAL-BASED	252	39.3	4.0	52.9	8.8
ALL RURAL	2549	14.2	0.8	77.7	12.4
FREESTANDING	1306	5.9	0.1	83.7	14.3
HOSPITAL-BASED	1243	23.0	2.1	68.2	9.3
OLD AGENCIES	1894	10.1	1.0	80.2	10.5
FREESTANDING	867	6.0	0.1	85.1	11.6
HOSPITAL-BASED	1027	20.6	2.1	70.6	9.1
NEW AGENCIES	655	10.9	0.2	80.4	16.9
FREESTANDING	449	5.7	0.0	83.0	20.3
HOSPITAL-BASED	206	34.7	1.4	55.9	11.6
BY: REGION					
OLD AGENCIES	4467	17.2	1.6	78.2	10.3
MIDWEST	1296	16.9	2.6	78.6	8.8
NORTHEAST	649	7.4	0.3	89.2	10.3
SOUTH	1057	17.0	1.2	80.1	12.0
WEST	662	26.4	4.1	81.4	8.4
NEW AGENCIES	2693	10.9	0.7	79.2	17.2
MIDWEST	607	15.2	1.0	73.1	10.9
NORTHEAST	247	19.6	2.4	80.2	9.9
SOUTH	1316	7.2	0.4	83.5	21.4
WEST	524	11.3	0.3	84.4	16.2

* New Agencies Are Those Without a 12-Month Cost Reporting Period Beginning in Federal FY 1994.

B. Percent of Costs Exceeding Per-Visit Limitations (Column Four)

Results from this column indicate that, for an HHA that reaches the per-visit limitation first, the average percent of the agency's costs exceeding the per-visit limitation for an HHA in the "all agencies" category is 1.3 percent after the behavioral offset. This relatively low number should not be surprising since the intent of section 4602 of the BBA is to control the soaring expenditures of the Medicare home health benefit that have been driven largely by increased utilization rather than the price per visit. For the all agencies category sorted by provider type, the average percent of freestanding HHAs exceeding the per-visit limitation is 0.3 percent; for hospital-based HHAs, it is 2.8 percent. This also should not be surprising as hospital-based HHAs have historically

had higher overhead costs. All discussion of the analysis of the per-visit limitation is based on the fact that HHAs in these categories reached the per-visit limitation and therefore are not affected by the per-beneficiary limitation. For the overall old agencies category (HHAs that filed a 12-month cost report that ended during Federal FY 1994), the average percent of the agency's costs exceeding the per-visit limitation is 1.6 percent; for freestanding HHAs, it is 0.4 percent; and for hospital-based HHAs, it is 2.7 percent. For the overall new agencies category (such as HHAs that did not have a 12-month cost reporting period ended in Federal FY 1994 or that entered the Medicare program after Federal FY 1994), the average percent of the agency's costs exceeding the per-visit limitation is 0.7 percent. For freestanding HHAs, it is 0.3 percent; and

for hospital-based HHAs, it is 4.1 percent.

For the urban areas HHA category, the average percent of the agency's costs exceeding the per-visit limitation is 1.5 percent. For freestanding HHAs, it is 0.4 percent; and for hospital-based HHAs, it is 3.0 percent. For the rural areas HHA category, the average percent of such agency's cost exceeding the per-visit limitation is 0.8 percent; for freestanding HHAs, it is 0.1 percent; and for hospital-based HHAs, it is 2.1 percent.

For the old agencies urban provider type category, the average percent of the agency's costs exceeding the per-visit limitation for freestanding HHAs is 0.5 percent; and for hospital-based HHAs, it is 2.9 percent. For the old agencies rural provider type, the average percent of the agency's costs exceeding the per-visit limitation for freestanding HHAs is 0.1

ATTACHMENT TO ANSWER 34

ORDER FOR SUPPLIES OR SERVICES						PAGE	OF	PAGES	
IMPORTANT: Mark all packages and papers with contract and/or order numbers.						1	56	//	
1. DATE OF ORDER 04/27/1999		2. CONTRACT NO. (if any) 743-9-607800		3. NAME OF COMBINE N/A					
3. ORDER NO. HCFA-99-0154		4. REQUISITION/REFERENCE NO. 743-9-607800		5. STREET ADDRESS					
5. ISSUING OFFICE (Address correspondence to) HEALTH CARE FINANCING ADMIN AGG/DCATS, C3-21-15 7500 SECURITY BOULEVARD BALTIMORE MD 212441850				6. CITY		7. STATE		8. ZIP CODE	
7. TO:				9. SHIP VIA					
10. NAME OF CONTRACTOR WILLIAM DOUVILLE				11. TYPE OF ORDER					
12. COMPANY NAME 3M HEALTH CARE				<input checked="" type="checkbox"/> a. PURCHASE REFERENCE YOUR QUOTE 4/23/99 <input type="checkbox"/> b. DELIVERY					
13. STREET ADDRESS 224-28-24 3M CENTER				Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheets, if any, including delivery as indicated. Submit for billing instructions on the reverse, this delivery order is subject to regulations contained on this side only of this form and is issued subject to the terms and conditions of the above-referenced contract.					
14. CITY ST. PAUL		15. STATE MIN		16. ZIP CODE 55144					
17. ACCOUNTING AND APPROPRIATIONS DATA 9596722 7590511 25.15				18. REQUISITIONING OFFICE CTR HEALTH PLANS & PROVIDERS					
19. BUSINESS CLASSIFICATION (Check appropriate box(es))									
<input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED									
20. P.O. POINT Destination		21. GOVERNMENT BR. NO.		22. DELIVER TO P.O. POINT ON OR BEFORE (Date) 12/31/1999		23. DISCOUNT TERMS Net 30			
24. INSPECTION Destination		25. ACCEPTANCE Destination							
17. SCHEDULE (See reverse for Rejections)									
ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	QUANTITY ACCEPTED (G)			
0001	TAX ID NUMBER: 410417775 CONTRACTOR TO EVALUATE COMMENTS RECEIVED IN RESPONSE TO PROPOSED USE OF AMBULATORY PAYMENT CLASSIFICATIONS FOR HOSPITAL OUTPATIENT AND AMBULATORY SURGICAL CENTER SERVICES IN ACCORDANCE WITH THE ATTACHED SCOPE OF WORK AND DELIVERABLES. THE NOT-TO-EXCEED AMOUNT IS BASED ON THE FOLLOWING LABOR CATEGORIES AND HOURS. HOURS Continued ...	540	HR	144.72	78148.80				
26. SHIPPING POINT		27. GROSS SHIPPING WEIGHT		28. INVOICE NO.					
29. NAME DHHS, HCFA, OFM, FSG		30. MAIL SERVICE TO:						179a. TOT. (Cont. page)	
31. STREET ADDRESS (or P.O. Box) Div. of Financial Operations, P.O. Box 7520									
32. CITY Baltimore		33. STATE MD		34. ZIP CODE 21207-0520				179b. GRAND TOTAL	
35. UNITED STATES OF AMERICA BY (Signature) <i>Susan C. Criser</i>				36. NAME (Typed) SUSAN CRISER TITLE: CONTRACTING/PROBING OFFICER					
AUTHORIZED FOR LOCAL REPRODUCTION Previous edition not valid				Procurement					

 OPTIONAL FORM 347 (Rev. 9/88)
 Prescribed by GSA, FPMR (41 CFR) 101-11.6

**ORDER FOR SUPPLIES OR SERVICES
SCHEDULE - CONTINUATION**

PAGE	OF
2	2 //

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 04/27/1999		CONTRACT NO.		ORDER NO HCFA-99-0154			
ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	QUANTITY ACCEPTED (G)	
	SENIOR CONSULTANT 158 SENIOR ANALYST 158 SENIOR PROGRAMMER 80 PHYSICIAN CONSULTANT 144 Obligated Amount: \$78,148.80						
0002	TRAVEL EXPENSES (NOT-TO-EXCEED) PERIOD OF PERFORMANCE: APRIL 27, 1999 - DECEMBER 31, 1999 Obligated Amount: \$8,856.00 HCFA PROJECT OFFICER: VIVIAN V. BRAXTON (410) 786-4571 I.A.WE. FAR 52.232-33, THE HEALTH CARE FINANCING ADMINISTRATION (HCFA) SHALL ONLY MAKE AN ELECTRONIC REIMBURSEMENT/PAYMENT FOR THIS PURCHASE ORDER. IF YOU HAVE NOT PREVIOUSLY REGISTERED YOUR ACH (AUTOMATED CLEARING HOUSE) BANK INFORMATION WITH HCFA, PLEASE FILL OUT THE ATTACHED FORM TITLED 'AUTHORIZATION AND PAYMENT INFORMATION FORM FOR ELECTRONIC FUNDS TRANSFER' SO THAT AN ELECTRONIC PAYMENT CAN BE MADE DIRECTLY TO YOUR BANK. FAILURE TO RESPOND MAY PROHIBIT HCFA'S ABILITY TO MAKE FUTURE AWARDS TO YOUR ORGANIZATION. AUTHORIZATION FORMS SHOULD BE FAXED TO THE ATTENTION OF JEAN KATZEM, FAX NO. 410-786-7259. IF YOU HAVE FURTHER QUESTIONS PLEASE CONTACT, JEAN KATZEM, (410) 786-5423. DIRECT QUESTIONS TO: LUCILLE FUSSELL-LEE (410) 786-5447 Total amount of award: \$87,004.80. The obligation for this award Continued ...				8856.00		

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(1))

HEW 7540-01-130-0002

50245-101

Procurement

OPTIONAL FORM 346 (REV. 6/95)

Prescribed by GSA
FAR (48 CFR) 23.213(h)

ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION						PAGE 3	OF 2 //
IMPORTANT: Mark all packages and papers with contract and/or order numbers.							
DATE OF ORDER 04/27/1999		CONTRACT NO.		ORDER NO. HCFA-99-0154			
ITEM NO. (A)	SUPPLIES OR SERVICES (B)	QUANTITY ORDERED (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)	QUANTITY ACCEPTED (G)	
	is shown in box 17(j).						
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(j))							

NNN 7540-01-153-0002 05045-101 OPTIONAL FORM 340 (REV. 080)
 Procurement Prescribed by GSA PAR (48 CFR) 53.213(a)

In both rules, HCFA invited comments on their construction and proposed use of APCs. In soliciting comments, HCFA discussed specific problems associated with calculating payment rates for APCs with aberrant data and solicited specific comments on such groups. HCFA also invited comments on the various options that they proposed in the hospital rule for grouping and paying medical visits.

Period of Performance

All tasks shall be completed by December 30, 1999

Project Task Requirements

The contractor shall supply all personnel, materials, supplies and support necessary to accomplish the work specified below except where a product/item is specified in the Schedule of Deliverables as the responsibility of HCFA. The contractor shall –

1. Review all comments identified by HCFA that were received in response to the hospital outpatient PPS and ASC proposed rules and which are specific to the proposed APCs to determine which of the specific issues and/or suggestions made by the commentators have clinical merit.
2. Based on this review, evaluate the identified APCs clinically and perform the appropriate statistical analyses to determine whether APC modifications are appropriate, e.g., moving specific procedure codes from one APC to another, subdividing specific APCs to create two or more APCs; and combining one or more specific APCs.
3. As a result of findings, recommend APC modifications to HCFA.
4. Ensure that the APC review and modification process results in groups that are similar both clinically and in terms of resource use.
5. Ensure that the APC review and modification process retains consistency among the surgical APCs for the ASC and hospital outpatient settings.
6. Retitle and renumber any APCs where modification results in redefining specific APCs.
7. Prepare written responses to all comments specific to the APCs for inclusion in the sections of the hospital outpatient PPS and ASC final rules.
8. Meet with government project officer and other pertinent staff identified by her to clarify tasks and discuss specific findings and recommendations.

APC Review and Modifications**Task Timetable**

<i>Time Period</i>	<i>Task</i>
5/99	Meet with HCFA staff to clarify tasks
5/17 – 7/16	Review comments Identify required modifications Perform clinical & statistical analysis of proposed modifications
7/20	Meet with HCFA staff to recommend modifications HCFA approves modifications
7/21 – 7/30	Modify APCs
7/31 – 8/9	Retitle and renumber APCs as necessary Draft technical APC text Draft written responses to APC comments
8/10 – 10/8	Re-evaluate APCs based on additional data/comments
10/9 – 10/18	Revise APC technical text Revise responses to APC comments
10/19 – 11/15	Refine APC groups and language
11/16 – 12/27	Final meeting with HCFA staff Wrap-up project

**APC Review and Modifications
Schedule of Deliverables**

Item	Deliverable	Due Date
1	Recommendations for APC modifications (from comments and analysis)	07/20/1999
2	APC modifications	07/30/1999
3	Revised APCs Draft of comments and technical APC text	08/09/1999
4	Re-evaluation of APCs	10/08/1999
5	Revised APC technical text and comments	10/18/1999
6	Refined APC groups and language	11/15/1999
7	Final meeting and project wrap-up	12/27/1999

At least three meetings with HCFA staff are planned as follows:

	<u>Date</u>	<u>Purpose</u>
#1	5/99	Clarify tasks and format of deliverables
#2	7/20/99	HCFA to review & approve proposed modifications
#3	12/27/99	Final review and project wrap-up

CBD SYNOPSIS

Transmission via CBD Express v1.1/W

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2. 0401!!
3. 99!!
4. GP0412008!!
5. 21244!!
6. 99!!
7. Health Care Financing Administration 7500 Security Blvd., Baltimore, MD. 21244-1850!!
8. 99 -- EVALUATION OF COMMENTS ON PROPOSED AMBULATORY PAYMENT CLASSIFICATIONS!!
9. N/A!!
10. N/A!!
11. Lucille Fussell-Lee, Contract Specialists (410) 786-5447!!
12. N/A!!
13. N/A!!
14. N/A!!
15. N/A!!
16. N/A!!

17. The Health Care Financing Administration (HCFA) intends to award on a sole source basis, under the Simplified Acquisition Procedures a firm fixed price award to the 3M Health Information Systems, Inc., 100 Barnes Road, Wallingford, CT 06492. HCFA intends to procure analytical and clinical support services from 3M Health Information Systems to evaluate comments received in response to two rules published in the Federal Register during 1998 concerning the proposed use of ambulatory payment classifications (APCs) as the basis for Medicare prospective payment for services furnished in hospital outpatient departments and ambulatory surgical center services (ASCs). The contractor will (1) evaluate comments on the proposed use of ambulatory payment classifications (APCs) as the basis for Medicare prospective payment for hospital outpatient and ambulatory surgical center services; (2) modify the APCs as warranted in response to the comments; and (3) prepare written responses to the comments which we expect to publish in the Federal Register in 1999 as part of the final rules for both the hospital outpatient prospective system and ASC prospective facility rates. The 3M Health Information Systems, Inc., is uniquely qualified to conduct this project. 3M has extensive experience in the design, construction, and application of ambulatory patient groups to prospective payment systems for the hospital outpatient setting. From 1988-1990, HCFA entered into a cooperative agreement with 3M to develop a classification system for outpatient services. HCFA submitted a report to the Congress in 1995, which stated that the ambulatory patients groups or APGs developed by 3M were the most promising hospital outpatient classification system, and

recommended adopting HCFA groups as the basis for the medical hospital outpatient. 3M has the analytical and clinical resources necessary to conduct this project. Moreover, it has the background and extensive experience in developing APGs and overseeing their implementation by other payors that distinguishes its qualifications from other potential contractors. 3M's unique qualifications would enable HCFA to complete this project within the tight time constraints under which it is operating to implement a PPS for hospital outpatient department services and a rebased payment system for ASC services as soon as possible after January 1, 2000. All responsible sources may submit capability statements in consideration to the Agency at the above address.



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